
**“EFFECT OF SODIUM FLUORIDE MOUTHWASH
ON TENSILE STRENGTH AND PERCENTAGE
ELONGATION OF ELASTOMERIC CHAINS AT
DIFFERENT INTERVALS AFTER ACTIVATION:
AN IN-VITRO AND IN-VIVO STUDY”**

**By
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Dissertation

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(BRANCH – V)**

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LIST OF ABBREVIATIONS

E-chain	-	Elastomeric chain
NaF	-	Sodium Fluoride
NaOH	-	Sodium Hydroxide

ABSTRACT

Introduction: Elastomeric chains became widely known among orthodontists due to their ease of use, reduced chair-side time, low cost, and high flexibility. Elastomeric chains can be used to close spaces in extraction sites as well as to close generalized spacing. Because of their widespread use in orthodontics, it is critical for orthodontists to understand their tensile qualities when they are under stress. If their dimensions change quickly, such as within 24 hours of use, their efficiency in the retraction system will suffer. Patients undergoing fixed mechanotherapy are usually prescribed mouthwashes, in addition to tooth brushing and other interdental aids. Hence, the orthodontist must understand how fluoride-containing mouthwash affects the tensile properties of the elastomeric chains. Hence, this study was conducted with the aim to determine the effect of 0.05 percent Sodium Fluoride mouthwash on the tensile strength and percentage elongation of elastomeric chains both in-vitro (i.e., exposed to air) and in-vivo (i.e., intraorally, in the mouth).

Materials and Methods: In the present study, open elastomeric chains of 3 units were tested. There were 4 groups; Group I was the control group, group II included elastomeric chains that were stretched in the external environment for 24 hours, Group III included E-chains that were stretched for 24 hours in the oral cavity, and Group IV included the E-chains that were stretched in the oral cavity for 3 weeks. Groups II, III, and IV were subdivided into two Subgroups A and B. The elastomeric chains in Subgroup A were immersed in Sodium Fluoride mouthwash (0.05%) while in Subgroup B, there was no exposure. For the in-vitro study, two personalized wooden test jigs were prepared, and the E-chains were stretched to 16 mm. For the in-vitro study, two crimpable hooks were placed one, distal to the canine bracket and the other one, mesial to the 1st molar tube. Patients in Subgroup A were instructed to use

mouthwash for 60 seconds twice daily. The elastomeric chains were removed after the specified time interval and transported to Praj Lab in Pune for tensile strength and percentage elongation testing.

Results: The mean tensile strength measured 24 hours after stretching (i.e., in Groups II A and B and Group III A and B) did not exhibit any significant decline. However, when compared to elastomeric chains stretched for 3 weeks (i.e., Group IV A- 24.94 ± 1.32 N and Group IV B- 25.17 ± 1.27 N), the tensile strength was significantly reduced ($p < 0.05$). The greatest tensile strength decrease reported was 24.94 ± 1.32 N, in Group IV A. In terms of percentage elongation, it was discovered that it was significantly increased in all groups. The elastomeric chain's initial length taken was 8 mm. The greatest elongation was recorded in Group IV A (14.2331 ± 0.93 mm) patients after 3 weeks in the oral cavity using mouthwash, which increased by 77.91%. There was no significant difference in the tensile strength and permanent elongation of E-chains when used with or without mouthwash.

Conclusion: Based on the recorded data and statistical analysis, the tensile properties of elastomeric chains are dependent on time, how long the chain was stretched out and maintained, exposure to sodium fluoride mouthwash, and whether the tests were conducted intraorally or outside. Elastomeric chains do not lose their tensile strength significantly after being stretched for 24 hours. The variation arises when they are stretched intraorally, as the decrease is greater in-vivo than in-vitro. When exposed to sodium fluoride mouthwash, the mean tensile strength of the elastomeric chains decreases, however, this decline is not significant. After being stretched for three weeks, there was a considerable loss of strength, implying that the elastomeric chains for the retraction system should be changed every three weeks. All elastomeric chain

groups experienced significant permanent elongation. However, the greatest elongation was observed after 3 weeks of intraoral exposure to Sodium Fluoride.

Keywords : Elastomeric chain(s), Sodium Fluoride Mouthwash(es), Tensile strength, Percentage Elongation, Force decay

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INTRODUCTION

Orthodontic therapy has progressed to new levels in terms of excellent treatment outcomes due to the rapid progress of orthodontic procedures and materials, resulting in the widespread usage of fixed orthodontic mechanotherapy. Fixed mechanotherapy allows for complete control over tooth alignment and precise force application, making it useful for the treatment of any tooth malalignment as well as multidisciplinary orthodontic, surgical, and prosthetic treatment. Treatment is not always limited to the use of brackets; orthodontic archwires and auxiliary parts are frequently required to apply precise and coordinated forces. For many years, elastic orthodontic components known as elastomers have been used as one of those auxiliary elements.¹⁴

Elastomers are a broad category of materials that quickly return to their original dimensions after deformation. The first known elastomer was natural rubber, which was most likely used by the historical Incan and Mayan civilizations. It was only used in limited situations due to its undesirable temperature behaviour and water absorption qualities. After Charles Goodyear invented vulcanization in 1839, natural rubber's popularity skyrocketed. Baker, Case, and Angle were the first to advocate for natural latex rubber elastics in orthodontics.¹⁶

Synthetic rubber polymers, which were developed from petro-chemicals in the 1920s, have a feeble molecular bond composed of primary and secondary linkages. When the system is at rest, it has a unique geometric configuration of folded linear molecule chains. When these molecular chains are extended or distorted, they spread out in an orderly linear shape at the expense of the secondary bonds. At a few points

along the molecular chains, cross connections of primary bonds are maintained. If the distraction provided by the chains is insufficient to cause the primary links to rupture, the extension will be released, allowing the chain to be restored to a passive state. The elastic limit is exceeded when the main bonds are broken, resulting in permanent deformation.¹⁶

Both ozone and UV radiation, which generate free radicals, are extremely harmful to synthetic polymers. The polymer's flexibility and "tensile strength" are reduced when exposed to free radicals. To counteract these problems and increase the shelf life of elastomeric materials, manufacturers have included antioxidants and anti-ozonates.¹⁶

Elastomers are used in orthodontics in a variety of shapes and sizes, the most common of which are separators, ligatures, rotating wedges, elastic threads, and chains.

Orthodontists have always desired simpler and easier ways for closure of spaces created by permanent tooth extraction. To close these extraction spaces, various mechanisms have been used. A few commonly used examples are closing loops, coil springs, elastics, and "elastomeric chains".¹

"Elastomeric chains" were originally employed in dentistry in the 1960s and have since become an important element of several orthodontic practices.¹ A linear polymer like polyurethane is formed by the chemical process which involves reaction of diisocyanate and a polyol, is used to make synthetic elastic chains. The properties of the material can vary from soft to rigid, elastic to brittle.⁵

"Elastomeric chains" provide light constant forces for anterior segment retraction, space closure in diastema cases, correction of a rotated tooth, midline correction, arch constriction, and traction of impacted teeth. They have numerous advantages over other materials in orthodontics, such as being inexpensive, hygienic, simple to use, and requiring little or no patient assistance.^{1,3,9,10,16}

Nevertheless, "elastomeric chains" have some disadvantages. When they are stretched and subjected to the oral cavity, they retain moisture and saliva, get discoloured, and undergo internal links breakdown, resulting in irreparable deformity. In many studies, it was discovered that, the "force decay" of "elastomeric chains" exposed to a test solution (pH 7.26) was significantly greater than that of an acidic solution (pH 4.95).¹⁷⁻²² These "elastomeric chains" are susceptible to strain while in use, lowering the force delivered by them, which is exacerbated in the oral environment.^{2,23-24} Because of this force loss, orthodontists have a difficult time determining the actual force that is acting on the teeth.¹⁶

Manufacturers have attempted to address their shortcomings since their introduction in the 1960s by changing the material composition (Power Chain, Rocky Mountain Orthodontics [RMO], RMO Europe, Strasbourg, France) or the design (Power Chain, Rocky Mountain Orthodontics [RMO], RMO Europe, Strasbourg, France) (Elast-O-Chain, TP Orthodontics Inc, La Porte, Ind). The focus of developing research has been to deliver light continuous and steady forces for a therapeutically significant time period of 4 to 8 weeks.¹⁰

According to previous studies, "elastomeric chains" lost 50% - 70% of its original force on the 1st day of application of load, with 30% - 40% of force remaining after three weeks.^{10,19-20,25-29} The literature is ambiguous about the amount of

“elastomeric chain” extension that might be required to achieve force levels that would be compatible with effective movement of the teeth due to the wide variation in initial force levels among manufacturers' devices. Researchers recommended a 50% to 75% extension after stretching some chains to 100% of its initial length, resulting in initial force levels of more than 450 gm. When fully distracted, other chains produce an appropriate force level of 300 gm.¹⁶ Andreasen and Bishara proposed that the synthetic elastomeric chain be overstretched to generate a significantly higher initial force in order to overcome the rapid loss of force.^{10,19} However, this may result in increased patient discomfort²⁵ as well as other problems, such as undermining resorption.³⁰ To reduce “force decay” over time, clinicians should stretch “elastomeric chains” into place more slowly, according to Kovatch et al.³¹ Young and Sandrik observed that prestretching “elastomeric chains” in air enhanced the residual force by 17 to 25% after 24 hours when compared to the un-prestretched controls.^{10,30}

Aside from manufacturing methods and composition, differences in time-dependent force loss between nominally similar products can be because of differences in the manufacturing process of the module such as die-cut stamping and injection moulding, additives might be present, and various other morphological (such as if the shape is an ellipsoid or it can be circular modules) or dimensions of the chains (such as presence or absence of an intermodular link)^{5,32-33}

Billmeyer proposed that polymeric materials can be permanently deformed by stretching of the molecular chain, if slippage occurs between neighbouring molecular chains, and scission of the molecular chain.³⁴ The material undergoes an immediate elastic deformation while being stretched. When the load is kept constant, there is

delayed elastic deformation and irreversible viscous deformation, resulting in percentage “elongation”.^{5,35}

After unloading, the elastic force is immediately restored, and the latent elastic force decays. The rate at which loading is done and the time span, for how long loading is done, as well as environmental factors, all have an impact on the tensile performance of elastomers.^{5,36-37}

Given the therapeutic importance of these materials in orthodontics, the behaviour of “elastomeric chains” in strain is of importance. If the dimensions of the material change quickly, such as within 24 hours of the start of loading, the chain’s dimension will be elongated for the entire time when used intraorally, impeding its performance in the retraction/ space closure mechanism. Tensile testing could be used to determine the chain's resistance to fracture in both directions. This feature could aid in calculating the likelihood of chain breakage as well as the effect of intraoral ageing on the material's strength.^{5,38} As a result, it is critical for orthodontists to know the mechanical properties of elastomeric materials in both in-vitro and in-vivo conditions in order to exert optimal forces and achieve the desired tooth movement in the shortest possible time.

Maintaining oral hygiene in patients undergoing orthodontic treatment becomes difficult, which has been a concern for decades. There is an increased risk of plaque accumulation and white spot lesions around the bracket margins and the gingival third of the teeth. To address this issue, many orthodontists recommend that patients use “mouthwash” as an additional aid in maintaining their oral hygiene.

“Mouthwashes” are commonly prescribed for patients undergoing fixed orthodontic treatment in addition to tooth brushing and other interdental aids. “Mouthwashes” have been employed for generations for wide range of medicinal purposes, but the rationale behind the use of chemical ingredients has only recently been subjected to scientific research and clinical trials. Dentists today work in a time when patients are more concerned about their oral health as well as their overall medical well-being, and they have become increasingly important as subjects' demand for maintaining oral hygiene has grown.^{39,40} It was originally known that fluoride treatment could decrease the risk of tooth decay, particularly in orthodontic patients who are prone to enamel demineralization around orthodontic attachments.^{11,41-44} However, studies have shown that fluoride in “mouthwash” may influence the force of “elastomeric chains”, resulting in insufficient tooth movement.⁴⁵⁻⁴⁶ As a result, the orthodontist must understand how fluoride-containing “mouthwash” affects the tensile properties of the “elastomeric chains”. Hence, this study was conducted with the aim to assess how the “Sodium Fluoride” (0.05%) “mouthwash” affected the “tensile strength” and percentage “elongation” of “elastomeric chains” both in-vitro (i.e., exposed to air) and in-vivo (i.e., intraorally, in the mouth).

AIM AND OBJECTIVES

AIM OF THE STUDY:

To compare and evaluate the effect of “Sodium Fluoride” “mouthwash” (0.05%) on the “tensile strength” and percentage “elongation” of “elastomeric chains”; in-vitro (i.e., exposed to air) and in-vivo (i.e., intraorally in saliva at body temperature, 37°C).

OBJECTIVES OF THE STUDY:

- (1) To assess experimentally the “tensile strength” of “elastomeric chains” before and after stretching in both in-vitro (i.e., exposed to air) and in-vivo environment (i.e., intraorally in saliva at body temperature, 37°C) and when subjected to a medium, namely, “Sodium Fluoride” “mouthwash” (0.05%) in both in-vitro (i.e., exposed to air) and in-vivo environment.
- (2) To assess experimentally the percentage “elongation” of “elastomeric chains” after stretching in both in-vitro (i.e., exposed to air) and in-vivo environment and when subjected to a medium, namely, “Sodium Fluoride” “mouthwash” (0.05%) in both in-vitro (i.e., exposed to air) and in-vivo environment.
- (3) To assess the effect of “Sodium Fluoride” “mouthwash” (0.05%) on the “tensile strength” of “elastomeric chains” in both in-vitro (i.e., exposed to air) and in-vivo environment.
- (4) To assess the effect of “Sodium Fluoride” “mouthwash” (0.05%) on the percentage “elongation” of “elastomeric chains” in both in-vitro (i.e., exposed to air) and in-vivo environment.

REVIEW OF LITERATURE

1) **Emanuel Braga, Gabriella Souza, Paula Barretto, Caio Ferraz and Matheus Pithon (JIOS 2019)** ⁴ examined how hot drinks (hot water, hot green tea, and hot coffee at $70 \pm 1^\circ\text{C}$) affected the degradation of orthodontic “elastomeric chains” tensile strength.

- They concluded that exposure to hot water, hot green tea, and hot coffee at $70 \pm 1^\circ\text{C}$ contributed to a statistically significant loss of strength of orthodontic "elastomeric chains" after 7 and 14 days.

2) **Patel A, Thomas B.(Journal of the World Federation of Orthodontists 2018)** ⁶ assessed and compared the in-vivo “force decay” of “elastomeric chains” produced by four different companies (Super Slick, Alastick, Memory chain and Dyna-Link) over a period of six weeks with the help of a digital force gauge.

They concluded that:

- One hour after placing the E-chain, the most significant force reduction was seen.
- By the end of six weeks, the force was almost constantly decreasing.
- The force lost in each “elastomeric chain” of various companies varied significantly.
- Three of four “elastomeric chains”—Memory chain by American Orthodontics, Alastick by 3M Unitek, and Super Slick by TP Orthodontics—had retained a substantial amount of force to cause canine retraction. Dyna-Link (by G&H Orthodontics), was the only “elastomeric chain” that had experienced such a significant “force decay” that it was unable to retract canine after six weeks.

- 3) **Matheus Melo Pithon, Dandara Andrade Santana, Kássio Henrique Sousa, Isa Mara Andrade Oliveria Farias (The Angle Orthodontist 2013)** ⁸ in their study examined the force of “elastomeric chains” affected by “mouthwashes” containing bleaching agents and those without in in-vitro setting.

They found that:

- The force loss was not significantly impacted by the interaction of the “elastomeric chains” with “mouthwashes” containing bleaching agents.
- The highest force reduction was seen within the first 24 hours.

- 4) **Baratieri C, Mattos CT, Alves Jr M, Lau TC, Nojima LI, Souza MM, Araujo MT, Nojima MD (Brazilian dental journal 2012)** ⁷ evaluated whether “elastomeric chains” “tensile strength” was altered by intraoral exposure and compared conventional (plastic chain) to enhanced chains (Memory Chain and Super Slick Chain)

They concluded that:

- After an initial 180 g of activation, in-vitro stretching of the “elastomeric chain” caused a “force decay” during the three-week testing period, and the greatest “force decay” was after the 1st hour.
- In the enhanced chains, Memory Chain and Super Slick Chain, the residual force and its percentage at every time period were higher than in the standard “elastomeric chain”, plastic chain.
- Only the enhanced chains continued to exert a force greater than 100 g after three weeks.

- 5) **T. Eliades, G. Eliades, N. Silikas and D.C. Watts (EJO 2004)** ⁵ assessed “elastomeric chains” “tensile strength” and percentage “elongation” both in in-vitro setting and in-vivo setting.

They concluded that:

- The “elastomeric chains” underwent permanent deformation indicated as “elongation” after being stretched in vitro. Because of the wide variety in the "elastomeric chain" form, thickness, and length of the links among specimens from the similar category, the structure or morphology of the "elastomeric chain" (open or closed) had no effect on its percentage “elongation”.
- The toughness of the specimens did not correspond to the “tensile strength” group rankings. The reason could be variances in specimen deformation while loading, which could have occurred either elastically or plastically.
- In terms of “tensile strength” and toughness, no correlation was found between control group, stretched in the air, and recovered elastic chain specimens.

- 6) **Evans KS, Wood CM, Moffitt AH, Colgan JA, Holman JK, Marshall SD, Pope DS, Sample LB, Sherman SL, Sinclair PM, Trulove TS. (AJODO 2017)** ¹ assessed if an unaltered “elastomeric chain” could keep moving teeth for 16-weeks and compared it to the remaining force for the same sample of “elastomeric chains”.

They concluded that:

- The altered site, where “elastomeric chain” was replaced at every four weeks, closed more quickly than the unaltered chain site, but the difference was statistically insignificant suggesting that the unaltered “elastomeric chains” continued to close spaces throughout the 16-week measurement period.

- They also compared the in-vivo data were to the in-vitro “force decay” measurements for the same “elastomeric chain” and found that a force lower than 100 grams had a clinical impact on tooth movement.

7) **Kim KH, Chung CH, Choy K, Lee JS, Vanarsdall RL. (AJODO 2005)** ⁹ studied how prestretching affected the time-dependent “force decay” of synthetic “elastomeric chains”.

They further testified that:

- The initial forces of the prestretched 5- & 6-units “elastomeric chain” were much lower than those of the corresponding controls, and within the first hour, there was significant “force decay”.
- A comparable rate of force depreciation was seen between the prestretched and control groups from 1 hour to 4 weeks.
- After 4 weeks, similar residual forces were recorded between the control and prestretched groups.

8) **Buchmann N, Senn C, Ball J, Brauchli L. (The Angle Orthodontist 2012)** ¹⁰ examined the rate of “force decay” when the initial strain is applied to commercially available elastic chains (3M Unitek, American Orthodontics, Dentaaurum, Forestadent, GAC,Ormco, Ortho Organizers Inc, Rocky Mountain Orthodontics)

They concluded that:

- In the first 24 hours, there was a significant decrease in force throughout the course of three weeks, but there was little loss after that up until three weeks.

- Loss of force depended solely on the type of chain being tested and not on initial activation.
- They stated that after 3 weeks, the force loss in the “elastomeric chains” from American Orthodontics, Ormco, and Rocky Mountain Orthodontics was only 40%.

9) **Ramazanzadeh BA, Jahanbin A, Hasanzadeh N, Eslami N. (Journal of Clinical Pediatric Dentistry 2009)** ¹¹ examined how “mouthwash” containing 0.05% “Sodium Fluoride” affects “elastomeric chains” elastic characteristics, which are often used in fixed orthodontic treatment.

They found that:

- Using NaF “mouthwash” increases the amount of distraction needed to generate 150g and 300g forces. However, the increase was not statistically significant for 150 g of force, but it was for 300 g of force, which is greater than the ordinary forces employed in orthodontics.
- Additionally, there were no appreciable changes in the “force decay” of “elastomeric chains” between “mouthwash” and saliva and saliva alone.
- The amount of “force decay” and distraction needed to apply 150 g and 300 g of force to the two-test media differs significantly between American Orthodontics and Dentaurem chains; as a result, American Orthodontics chains required more distraction and had greater “force decay” than Dentaurem chains.

10) **Hassan HM, Mudhir AM. (Journal of Duhok University 2020)**¹² assessed the effect of commercially used “mouthwash” (kin, Vitis, Perio Aid, Splat White “mouthwashes”) on the “force decay” of orthodontic “elastomeric chains”.

They concluded that:

- Daily use of “Sodium Fluoride” “mouthwash” could enhance “force decay” of “elastomeric chains” on 1st and 28th day following activation.
- Splat “mouthwash” had the least impact on the rate at which “elastomeric chains” degrade over time, while Kin and vitis induce the highest rate of “force decay”.

11) **Menon VV, Madhavan S, Chacko T, Gopalakrishnan S, Jacob J, Parayancode A (Journal of Pharmacy & Bioallied Sciences 2019)**¹³ evaluated the impact of various “mouthwashes” and their active ingredients on the “force decay” of “elastomeric chains”. This study examined the effects of Listerine, Colgate Phos-Flur, Clohex Plus “mouthwashes”, 26.9% alcohol, 0.04% “Sodium Fluoride”, and 0.2% chlorhexidine on the “force decay” of “elastomeric chains”.

They concluded that:

- In 28 days, “elastomeric chains” experienced the greatest “force decay” (71.61%) due to Listerine “mouthwash” (alcohol-based). The least amount of “force decay” (64.91%) in “elastomeric chains” is brought on by the chlorhexidine based Clohex Plus “mouthwash”. Colgate Phos-Flur, a fluoride-based product, results in a 65.22% “force decay” on “elastomeric chains”.
- By the course of the 28-day period, alcohol (26.9%), a component of Listerine, was responsible for 69.26% of the “force decay”. The Colgate Phos-Flur ingredient NaF (0.04%) was the cause of 64.2% of the force deterioration. The

ingredient in Clohex Plus “mouthwash”, chlorhexidine (0.2%), contributed to 64% of the “force decay”.

- 12) **Kardach H, Biedziak B, Olszewska A, Golusińska-Kardach E, Sokalski J.** (*Adv Clin Exp Med* 2017) ¹⁴ evaluated and compared the “tensile strength” of plastic and elastomeric memory chains in-vitro immersed in 37°C artificial saliva.

They confirmed that:

- To maintain a moderately consistent force value, the “elastomeric chain” used in orthodontic treatment must be changed every four weeks.
- Due to a lower rate of mechanical and elastic property loss than plastic chains, memory chains are more efficient in orthodontic therapy.

- 13) **Sonis AL, Van der Plas E, Gianelly A.** (*AJO* 1986) ¹⁵ assessed the effects of nylon-covered latex thread on canine retraction rates along a continuous arch wire in vivo using a Class I force system and compared to those of several elastomeric auxiliaries (Unitek elastic thread, Unitek Alastik thread and Rocky Mountain chain)

They concluded that:

- It produced roughly equal amounts of tooth movement; thus, the clinician's decision to use one of these systems must be based on other factors like patient hygiene, comfort, and operator’s manipulation.
- In comparison to elastic thread, they found that the elastomeric auxiliaries were more hygienic and simpler to use.

MATERIALS AND METHODS

MATERIALS AND ARMAMENTARIUM

- 1) “Elastomeric chains” (Optima Flexichain Latex-free, USA)
- 2) Personalized Wooden Test Jigs
- 3) Steel Finishing Nails
- 4) Metal Scale
- 5) Mechanical Divider
- 6) Colgate Plax “mouthwash” (NaF 0.05%)
- 7) Crimpable Hooks
- 8) Universal testing machine

STUDY DESIGN:

In-Vitro and In-Vivo Study

SOURCE OF DATA/ LABORATORY DETAILS:

- The study will be conducted in the Department of Orthodontics and Dentofacial Orthopaedics, “KLE VK institute of Dental Science, KLE Academy of Higher Education and Research, Belagavi.”
- The “tensile strength” and percentage “elongation” of “elastomeric chains” will be assessed at Praj Metallurgy Laboratory, Pune, Maharashtra

SAMPLE SIZE ESTIMATION

FORMULA

The sample size (n) is derived by using the “comparing two means” formula:

$$n = \frac{(\sigma_1^2 + \sigma_2^2 / \kappa) (Z_{1-\alpha/2} + Z_{1-\beta})^2}{\Delta^2}$$

Where,

- σ_1 = standard deviation of Group 1,
- σ_2 = standard deviation of Group 2
- Δ = difference in group means (master article reference – Eliades T et al)
- Δ = difference in group means (master article reference – Eliades T et al)
- κ = ratio = $n_2/n_1 = 1$
- $Z_{1-\alpha/2}$ = two-sided Z value (eg. $Z=1.96$ for 95% confidence interval)
- $Z_{1-\beta}$ = power

Substituting the values in the above formula,

$$n = \frac{\{(1.9)^2 + (9)^2\} (1.96 + 0.84)^2}{(25.0 - 19.5)^2}$$

A sample size of **21.79~ 22 specimens** in each group is derived, considering 4 groups, a total sample size of 88 specimens is derived.

METHODOLOGY:

The study was conducted in the “Department of Orthodontics and Dentofacial Orthopaedics, KLE VK Institute of Dental Science, KLE Academy of Higher Education and Research, Belagavi.” Ethical clearance was obtained from the institution. The sample size for this prospective in-vivo and in-vitro study was calculated to be 88 specimens, comprising 22 specimens in each of the 4 groups. Patients who visited the Department of Orthodontics and Dentofacial Orthopaedics, KLE VK Institute of Dental Science, Belagavi, were included in the in-vivo study. Informed consent was obtained from all patients, according to the recommendations of our ethics committee at KLE VK Institute of Dental Science, KAHER.

The inclusion and exclusion criteria of the study is mentioned in Table 1 and Table 2 respectively.

INCLUSION CRITERIA:

IN-VITRO	IN-VIVO
<ul style="list-style-type: none">• "Elastomeric chains" within the expiration dates.• Stored in sealed plastic packages.	<ul style="list-style-type: none">• Orthodontic treatment involving first premolar extraction in all the quadrants.• Pre-adjusted edgewise appliance therapy• After the levelling and aligning phase of orthodontic treatment.• 0.019" X 0.025" stainless steel (SS) archwires in the upper and lower arches.• Good oral hygiene.• Patients willing to sign the previously approved informed consent form.

Table 1: Inclusion criteria of the in-vitro and in-vivo study.

EXCLUSION CRITERIA:

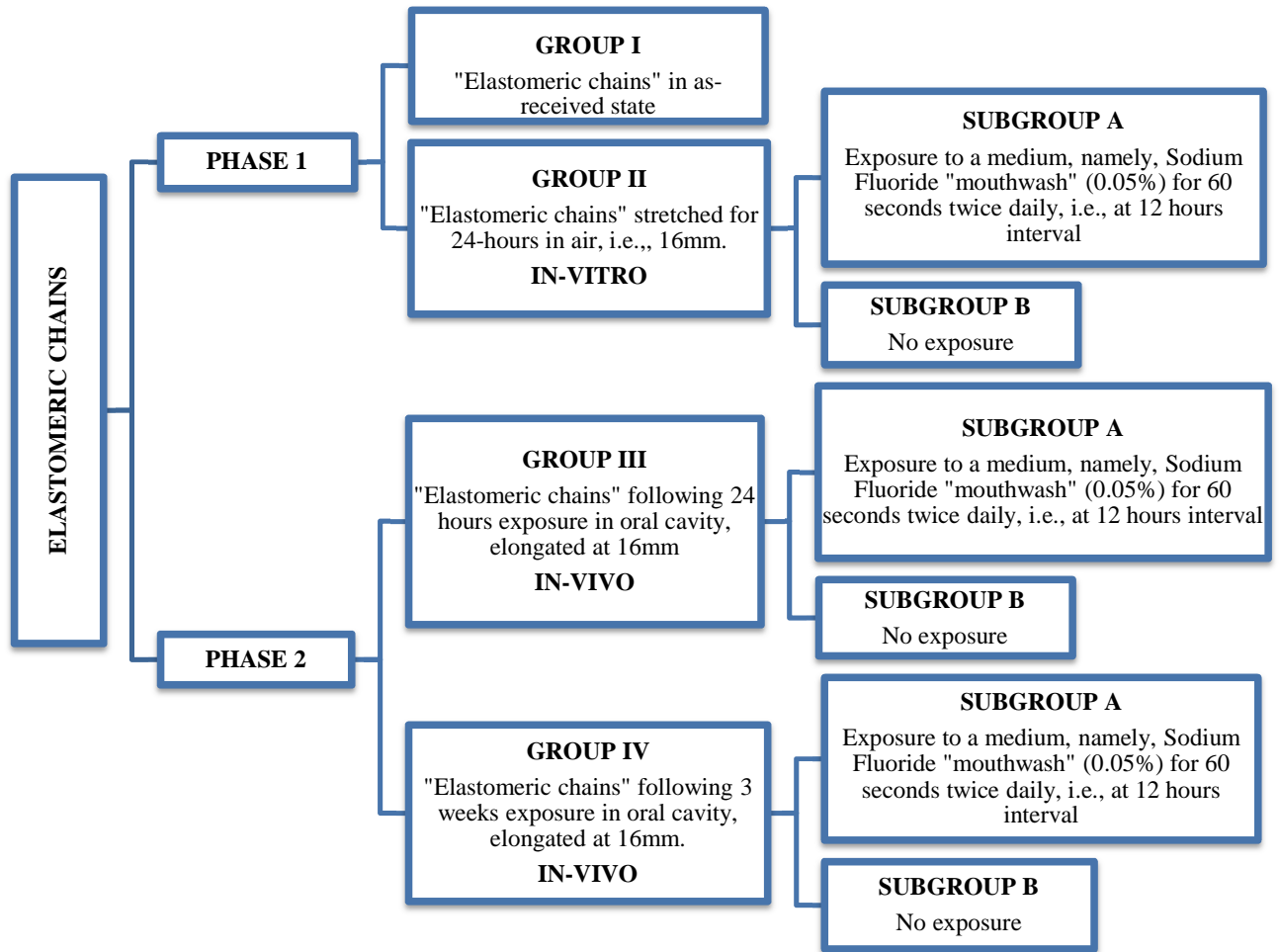
IN-VITRO	IN-VIVO
<ul style="list-style-type: none">• "Elastomeric chains" stored in improper conditions.• Deformed elastomeric chains.	<ul style="list-style-type: none">• Orthodontic treatment not involving first premolar extraction.• Subjects with broken or missing elastomeric chains.• Subjects with systemic diseases.• Subjects with poor oral hygiene.

Table 2: Exclusion criteria of the in-vitro and in-vivo study.

In this prospective, experimental study, open “elastomeric chains” (Optima Flexichain latex-free; Desires) i.e., with the intermodular link of 3 units were included. The samples were obtained by gently cutting 3 loops of “elastomeric chain” from the spool, using a pin and ligature cutter. Segment cutting was always done in the middle portion of the fourth link at each of its ends so that no damage to the structure of “elastomeric chains” occur during cutting.^{4,5}

Stretching of the elastomeric samples was avoided while cutting as this could have incorporated strain in the elastomeric material before the testing. The specimens weren’t pre-stretched. The segments were stretched to 16mm, i.e., the distance between the middle of the buccal surfaces of canine and second premolar.⁶

The specimens were classified as follows:



For the in-vitro study, two personalized wooden test jigs were constructed with 11 pairs of steel finishing nails placed 16 mm apart on each jig, which is the distance between the middle of the buccal surfaces of canine and second premolar.⁶

The specimens were stretched along the horizontal length. The two jigs were labelled as Subgroup A and Subgroup B. Subgroup A was immersed in “Sodium Fluoride” “mouthwash” 0.05% (Colgate Plax) solution for 60 seconds twice at an interval of 12 hours while Subgroup B was kept exposed to air.

For the in-vivo component, 0.022-inch slot stainless steel straight wire bracket kit with a MBT prescription (3M, Unitek) was used in all the patients. All first premolars were extracted in two stages in all patients. The first premolars on the same side, maxillary and mandibular, were extracted at the same time, followed by extraction on the contralateral side 5 days later. To ensure the patient's comfort, all first premolars were extracted about a week before beginning orthodontic treatment. Both arches were initially aligned and leveled using nickel-titanium archwires until 0.019" X 0.025" stainless steel wire was reached.

Two crimpable hooks with a predetermined distance of 16mm between them were attached and crimped to the 0.019" X 0.025" stainless steel archwire. One hook was crimped distal to the canine bracket while another one was crimped mesial to the first molar tube. The distance of 16 mm was measured using a mechanical divider. For all subjects, the same elastomeric chain (Optima Flexichain Latex-free, USA) was used. Sectional chains of three units were stretched and placed on both sides of the arch, resulting in four specimens.

Patients in Group III were required to report to the orthodontist the following day (after 24 hours). These patients were then randomly assigned to subgroups (Subgroup A and Subgroup B). Patients allocated in Subgroup A were prescribed “Sodium Fluoride” “mouthwash” 0.05% (Colgate Plax) twice for 60 seconds at an interval of 12 hours while patients belonging to Subgroup B were asked not to use any “mouthwash”. The elastomeric chain was removed and placed in an airtight container and shipped to the Praj Metallurgical Laboratory in Pune, Maharashtra for testing. Patients in Group IV were asked to report to the orthodontist after 3 weeks. The orthodontist texted Subgroup A subjects in the morning and at night to remind them to use the “mouthwash” as directed. The subject was disqualified from the study if the subject missed his or her appointment or appeared at his or her appointment with the elastomeric chain either broken or missing.

Calculation of percentage “elongation”:

The original length (L_0) of the retrieved samples from the spool was measured using a mechanical divider and metal scale. All specimens that were placed intraorally were washed with large volumes of distilled water to eliminate poorly attached intraorally produced integuments. When the testing was completed, the final length (L) of the sample was measured by using a mechanical divider and metal scale. This value was obtained in millimeters. The percentage “elongation” was calculated (in percentage) as:

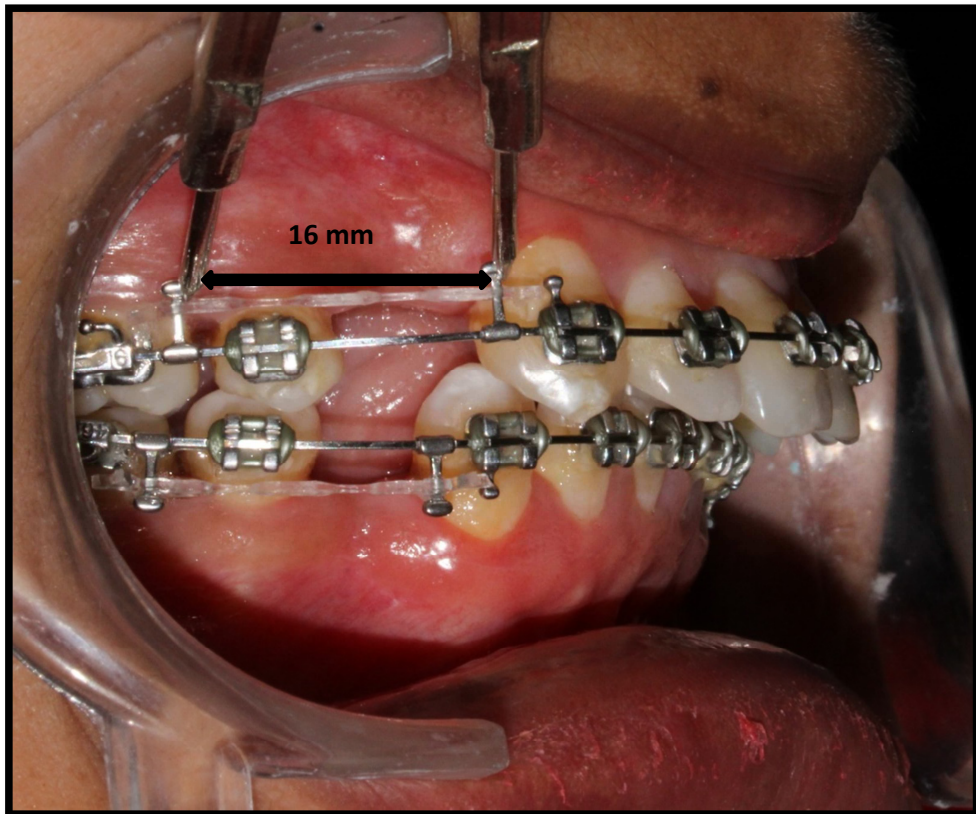
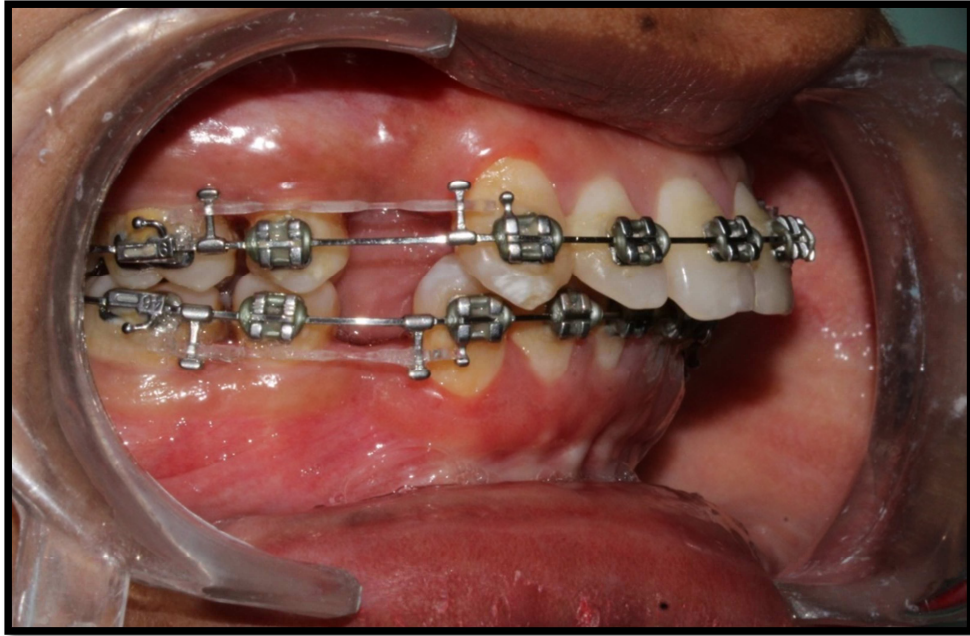
$$\Sigma = [(L - L_0) / L_0] \cdot 100$$

Calculation of “Tensile Strength”:

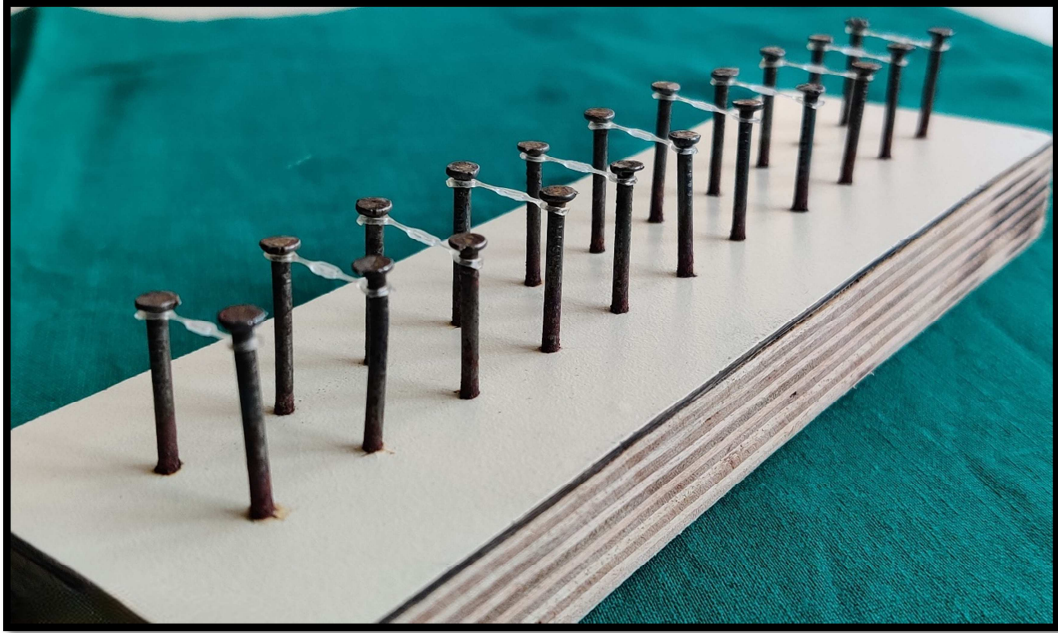
The specimens after the experiment were transported to Pune in vacuum containers. They were calibrated in Universal Testing Machine and then they were extended at a rate of 5 mm per minute until breakage. The testing machine comprised of two stainless-steel wire hooks and an elastic chain attached to the hooks. The tensile stress was applied to the samples of the “elastomeric chain” and the breaking force was measured for each sample. It was measured in Newton (N).

STATISTICAL TEST:

- 1) Data obtained was entered in Microsoft Excel 2007/2013
- 2) Descriptive and Frequency analysis will be done by using Statistical Product and Service Solution (SPSS) (v.21.0) software.
- 3) Unpaired t-test was performed to determine the significant differences between baseline and follow-up time period
- 4) p value of <0.05 will be considered statistically significant at 95% confidence intervals.







RESULT

Table 1.1: Mean “tensile strength” (N) of the “elastomeric chains” (submerged in “mouthwash”) stretched by 100% extension of their original length

With “mouthwash” (E)		Number	Mean	SD	Mean Difference	t-value	p-value
In-Vitro	Group I (Standard)	11	26.66	0.95	0.13	0.862061	0.129204
	Group II A (24 hours in the air)	11	26.53	2.05			
In-Vivo	Group I (Standard)	11	26.66	0.95	0.17	-0.51	0.960
	Group III A (24 hours in mouth)	11	26.49	1.18			
In-Vivo	Group I (Standard)	11	26.66	0.95	1.72	2.882	0.009*
	Group IV A (3 weeks in mouth)	11	24.94	1.32			
In-Vivo	Group III A (24 hours in mouth)	11	26.49	1.18	1.55	2.22194	0.00843*
	Group IV A (3 weeks in mouth)	11	24.94	1.32			

Graph 1.1: Mean “tensile strength” (N) of the “elastomeric chains” (submerged in mouthwash) stretched by 100%

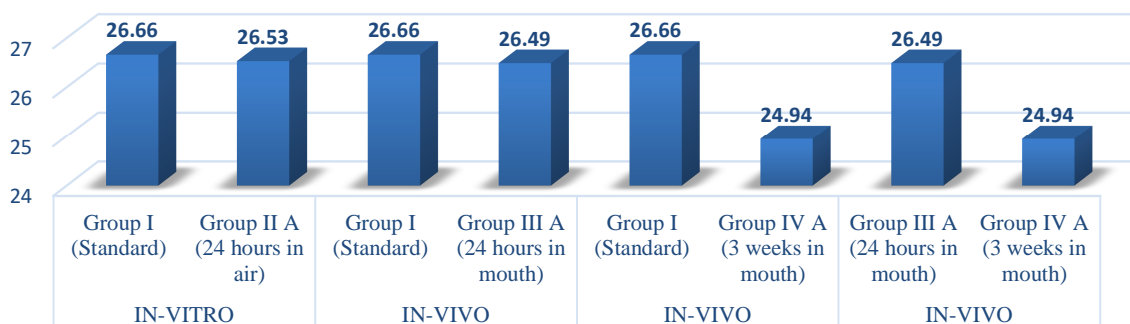


Table 1.2: Mean “tensile strength” (N) of the chains (with no exposure) stretched by 100% extension of their original length

Without “mouthwash” (NE)		Number	Mean	SD	Mean Difference	t-value	p-value
In-Vitro	Group I (Standard)	11	26.66	0.95	0.08	0.371	0.16362
	Group II B (24 hours in the air)	11	26.58	1.64			
In-Vivo	Group I (Standard)	11	26.66	0.95	0.14	-1.785	0.089
	Group III B (24 hours in mouth)	11	26.52	1.39			
In-Vivo	Group I (Standard)	11	26.66	0.95	1.49	2.495	0.021*
	Group IV B (3 weeks in mouth)	11	25.17	1.27			
In-Vivo	Group III B (24 hours in mouth)	11	26.52	1.39	1.35	4.00517	0.00145*
	Group IV B (3 weeks in mouth)	11	25.17	1.27			

Graph 1.2: Mean “tensile strength” (N) of the chains (with no exposure) stretched by 100%

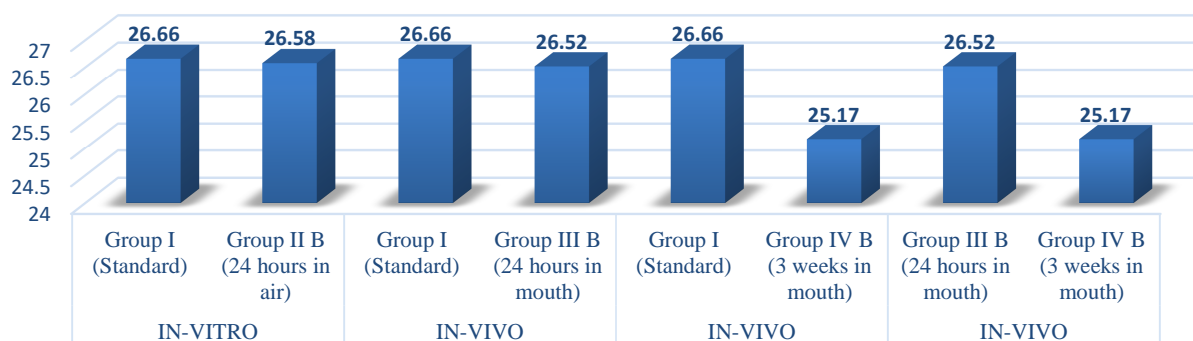


Table 2.1: Mean “elongation” (mm) of chain groups (submerged in “mouthwash”) after stretching by 100% extension of their original length

With “mouthwash” (E)		Number	Mean	SD	Mean Difference	t-value	p-value
In-Vitro	Group I (Standard)	11	8	0	-1.915	-	0.000*
	Group II A (24 hours in the air)	11	9.915	0.34423			
In-Vivo	Group I (Standard)	11	8	0	-4.267	-24.73	0.000*
	Group III A (24 hours in mouth)	11	12.267	0.57226			
In-Vivo	Group I (Standard)	11	8	0	-6.23309	-22.21	0.001*
	Group IV A (3 weeks in mouth)	11	14.2331	0.93047			
In-Vivo	Group III A (24 hours in mouth)	11	12.2670	0.57226	-1.96609	-	0.000*
	Group IV A (3 weeks in mouth)	11	14.2331	0.93047			

Graph 2.1: Mean "elongation" (mm) of chain groups (with mouthwash) after stretching by 100%

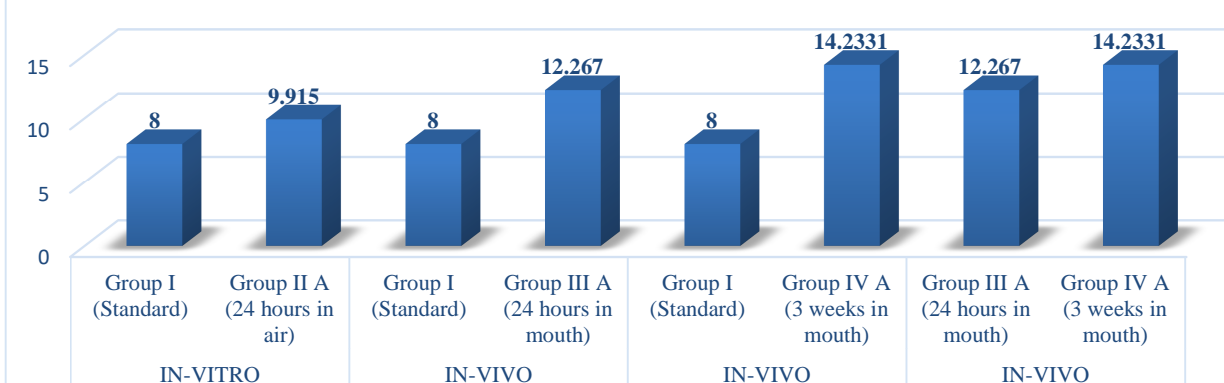


Table 2.2: Mean “elongation” (mm) of chain groups (with no exposure) after stretching by 100% extension of their original length

Without “mouthwash” (NE)		Number	Mean	SD	Mean Difference	t-value	p-value
In-Vitro	Group I (Standard)	11	8	0			
	Group II B (24 hours in the air)	11	9.8419	0.20491	-1.84187	-29.812	0.001*
In-Vivo	Group I (Standard)	11	8	0			
	Group III B (24 hours in mouth)	11	12.1558	0.90663	-4.15582	-15.203	0.000*
In-Vivo	Group I (Standard)	11	8	0			
	Group IV B (3 weeks in mouth)	11	13.9547	1.22093	-5.95475	-16.176	0.001*
In-Vivo	Group III B (24 hours in mouth)	11	12.1558	0.90663			
	Group IV B (3 weeks in mouth)	11	13.9547	1.22093	-1.79893	-3.923	0.001*

Graph 2.2: Mean "elongation" (mm) of chain groups (with no exposure) after stretching by 100%

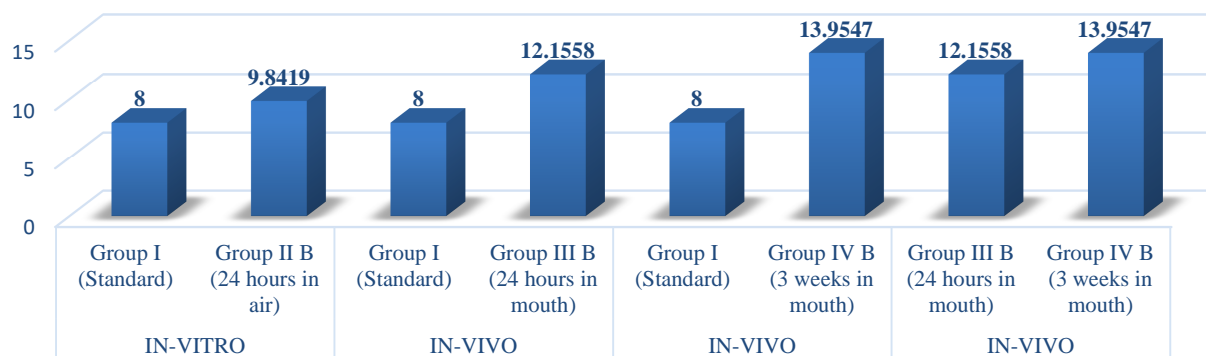


Table 3: Comparison of Mean “elongation” (mm) of chain sub-groups after stretching by 100% extension of their original length

Comparison Groups		Number	Mean	SD	Mean Difference	t-value	p-value
In-Vitro	Group II A (24 hours in the air)	11	9.9150	0.34423	.07313	0.605	0.552
	Group II B (24 hours in the air)	11	9.8419	0.20491			
In-Vivo	Group III A (24 hours in mouth)	11	12.2670	0.57226	.11118	0.344	0.734
	Group III B (24 hours in mouth)	11	12.1558	0.90663			
In-Vivo	Group IV A (3 weeks in mouth)	11	14.2331	0.93047	.27835	0.601	0.554
	Group IV B (3 weeks in mouth)	11	13.9547	1.22093			

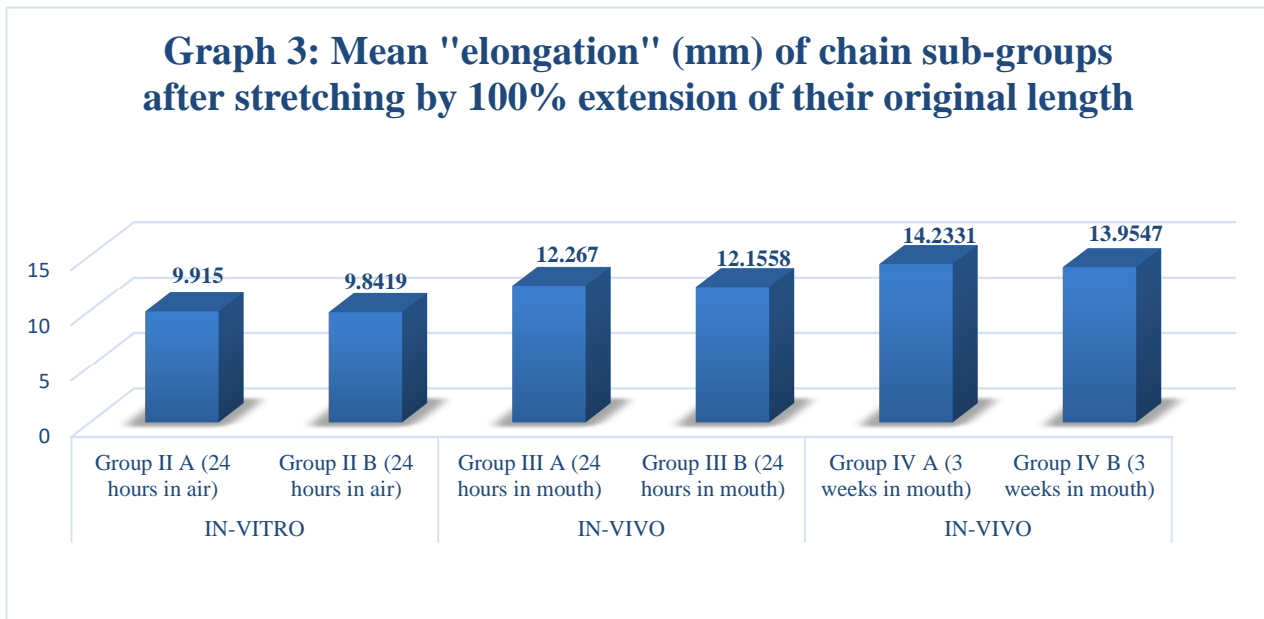
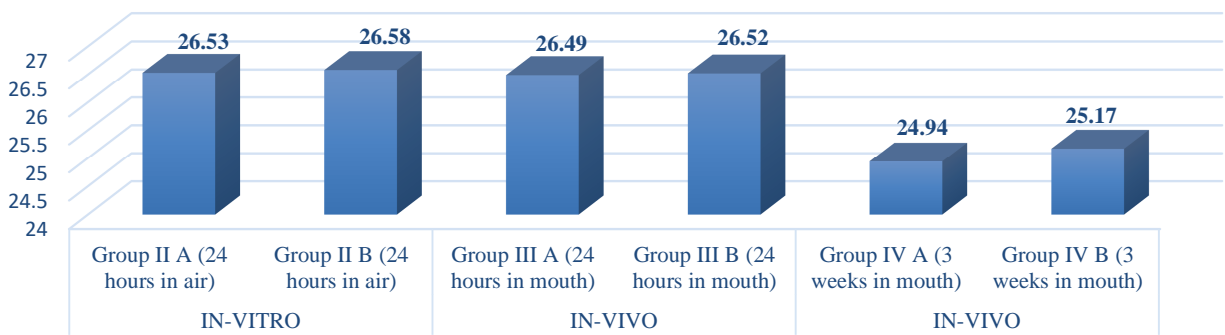


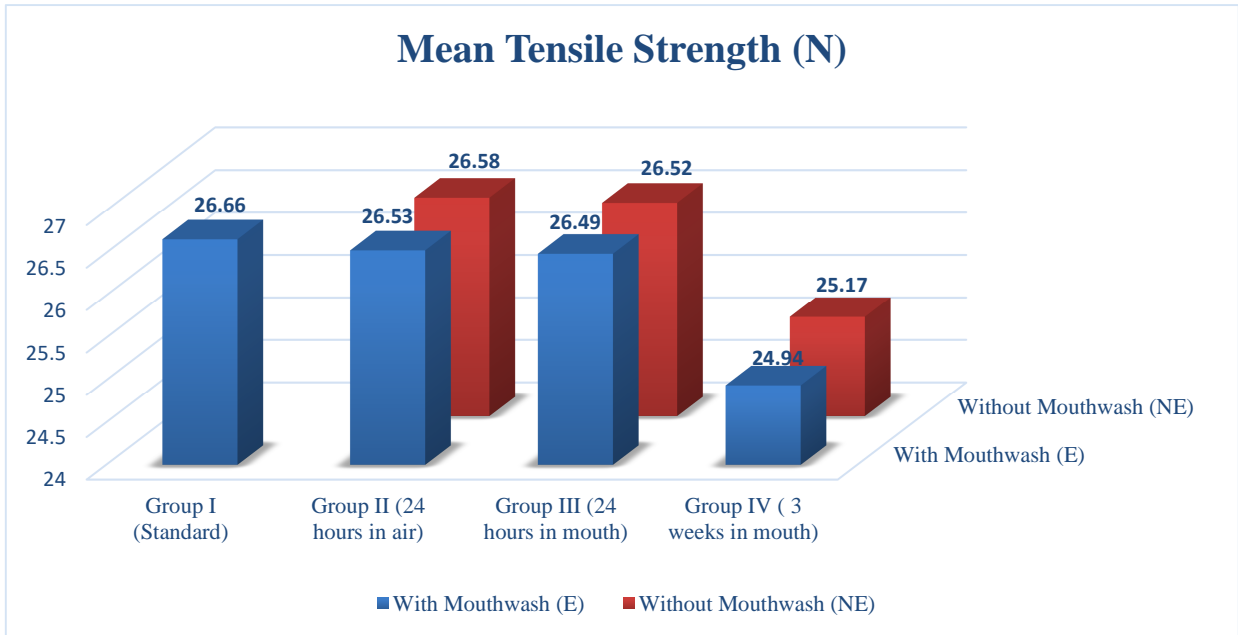
Table 4: Comparison of Mean “tensile strength” (N) of the chains’ subgroups stretched by 100% extension of their original length

Comparison Groups		Number	Mean	SD	Mean Difference	t-value	p-value
In-Vitro	Group II A (24 hours in the air)	11	26.53	2.05	-0.05	-	0.19774
	Group II B (24 hours in the air)	11	26.58	1.64			
In-Vivo	Group III A (24 hours in mouth)	11	26.49	1.18	-0.03	-1.598	0.07056
	Group III B (24 hours in mouth)	11	26.52	1.39			
In-Vivo	Group IV A (3 weeks in mouth)	11	24.94	1.32	-0.23	-	0.31201
	Group IV B (3 weeks in mouth)	11	25.17	1.27			

Graph 4: Mean “tensile strength” (N) of the chains’ subgroups stretched by 100% extension of its original length



Graph 5: Mean “tensile strength” (N) of the “elastomeric chains”



Graph 6: Mean “elongation” (in mm) of the “elastomeric chains”

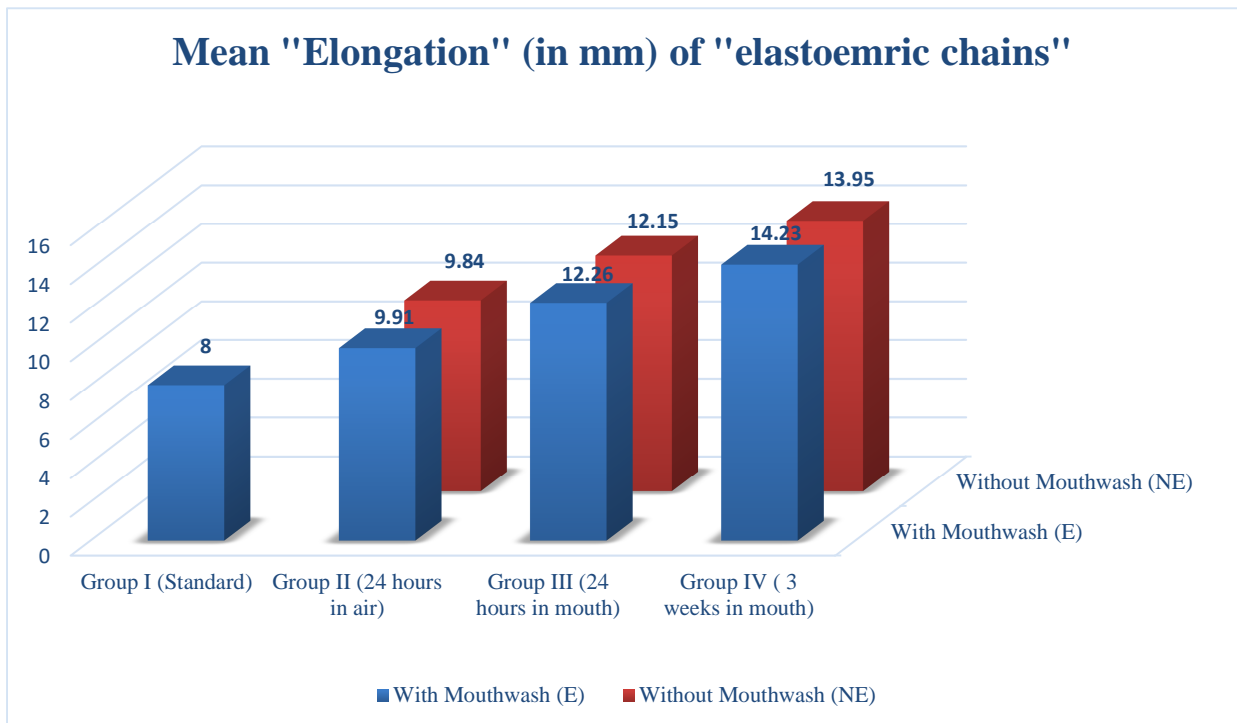


Table 1.1 and Graph 1.1 shows the mean “tensile strength” of the “elastomeric chains” that were immersed in “mouthwash” when stretched to 100% of their initial length. When the “tensile strength” of Group I (as-received) “elastomeric chains” is compared to Group II A (after 24 hours in the air), it is reduced to 26.53 ± 2.05 N, but not significantly. It was seen that the “tensile strength” of Group III A (26.49 ± 1.18 N) is slightly less than the “tensile strength” of Group II A (26.53 ± 2.05 N). “Tensile strength” was lowered further when compared to Group III A (26.49 ± 1.18 N), although the difference was not statistically significant. When the “tensile strength” of Group IV (24.94 ± 1.32 N) was compared to Group I, it was determined that the decline was statistically significant ($p < 0.05$). A comparison of Group III A and Group IV A found that the decrease in Group IV A (24.94 ± 1.32 N) was statistically significant ($p < 0.05$).

Table 1.2 and Graph 1.2 denotes the comparison of “elastomeric chains” of different groups compared when there was no exposure to “mouthwash”. When Group I (26.66 ± 0.95 N) was compared with Group II B (26.58 ± 1.64 N) and III B (26.52 ± 1.39 N), there was no significant reduction in the “tensile strength”, although the “tensile strength” of Group III B (26.52 ± 1.39 N) was slightly less than Group II B (26.58 ± 1.64 N). The “tensile strength”, however, significantly decreased in Group IV B (3 weeks in-vivo). to 25.17 ± 1.27 N when compared with Group I. After three weeks in the mouth, there was a statistically significant decrease in Group IV B (25.17 N) when Group III B and Group IV B were compared.

Table 2.1 and Graph 2.2 compares the mean “elongation” (measured in millimeters) of the “elastomeric chains” that were immersed in “mouthwash” after

they had been stretched by 100%. In all of the groups, a statistically significant increase in percentage “elongation” was seen. The amount of increase in the “elongation” of these “elastomeric chains” after 24 hours in air (Group II A) was almost 24%, and in mouth (Group III A) was 53.3%. The increase in length is higher in-vivo as compared to in the external environment. The highest percentage “elongation” was seen in Group IV A, i.e., 14.2331 ± 0.93 mm which was increased by almost 80% of its original length. When compared between Group III A and IV A, it was observed that there was only slight, but significant increase by 16%.

Following 100% “elongation”, Table 2.2 and Graph 2.2 compares the mean “elongation” (in mm) of the “elastomeric chains” with no “mouthwash” exposure. In all the groups, it was seen that there was significant permanent “elongation”. When we see, Group II B, which was tested after 24 hours of stretching in the air, the percentage “elongation” was 23% and in Group III B which was tested after 24 hours of stretching in the mouth, the percentage “elongation” was 51.9%. which is higher than Group II B. However, after 3 weeks of stretching in the mouth, Group IV B had the highest percentage “elongation”, reaching 13.9547 ± 1.22 mm, and increased by 74.4 %. When Group III B is compared to Group IV B, there is slight, but significant increase in the percentage “elongation” by 14.8%, which was observed in Group IV B.

Table 3 and Graph 3 represents a comparison of the mean “elongation” (in mm) of “elastomeric chains” within the subgroups. Group II A represents “elastomeric chains” that were stretched for 24 hours while submerged in “mouthwash”, and Group II B represents “elastomeric chains” stretched for 24

hours that had no exposure to “mouthwash”. There was slight increase in the percentage “elongation” in Group II A by 7.3%, although this “elongation” was not statistically significant. Similarly, Group III A was compared with Group III B, and Group IV A was compared with Group IV B, it was observed that there was an increase in the groups which were submerged in “mouthwash” (i.e., Group III A and Group IV A) by 0.9% and 1.9% respectively, but this increase was not statistically significant. The highest increase in the “elongation” was seen in Group IV A (14.2331 mm), i.e., “elastomeric chains” submerged in “mouthwash” and stretched for 3 weeks intraorally.

Table 4 and Graph 4 compare “elastomeric chains” within the subgroups based on their mean “tensile strength” (N). when Group II A (submerged in “mouthwash” and stretched for 24 hours in the air) and Group II B (no exposure to “mouthwash” and were stretched for 24 hours in the air) were examined, it was discovered that the “tensile strength” of the “elastomeric chains” that were submerged in “mouthwash” decreased slightly, but this drop was not statistically significant. Similarly, when Group III A (submerged in “mouthwash” and stretched for 24 hours intraorally) was compared to Group III B and Group IV A was compared to Group IV B, a decrease in “tensile strength” was found in the groups that were submerged in “mouthwash” (i.e., Group III A and Group IV A), however, this decrease was not statistically significant.

Graph 5 represents the mean “tensile strength” measured in Newton of the “elastomeric chains” of all the groups. By this graph, we can see the “tensile strength” of Group I is 26.66 ± 0.95 N. As we stretched the chain for 24 hours in the air and

submerged it in “Sodium Fluoride” “mouthwash”, i.e., Group II A, the “tensile strength” is reduced to 26.53 ± 2.05 N and when there is no exposure to “mouthwash”, i.e., Group II B, the “tensile strength” is reduced to 26.58 ± 1.64 N. We can see that the reduction is seen in both subgroups A and B but the mean “tensile strength” is slightly more reduced in Group II A (26.53 ± 2.05 N) as compared to Group II B (26.58 ± 1.64 N). When the “elastomeric chains” were extended in the mouth for 24 hours, we observed that the reduction in “tensile strength” observed is even higher. Group III A (E-chain in the mouth for 24 hours and subjected to “mouthwash”) has a “tensile strength” of 26.49 ± 1.18 N and in Group III B (E-chain in the mouth for 24 hours and no exposure) has a “tensile strength” of 26.52 ± 1.39 N. A similar pattern is observed here as well. But we can also observe that the “tensile strength” tested in-vivo (Group III A and B) are comparatively lesser than the groups tested in-vitro (Group II A and B). On further loading the chain for 3 weeks intraorally, we observed that there was a significant drop in the “tensile strength” with “mouthwash” (Group IV A = 24.94 ± 1.32 N) and without “mouthwash” (Group IV B = 25.17 ± 1.27 N).

Graph 6 represents the mean “elongation” measured in millimeters of the “elastomeric chains” of all the groups. The mean length of the elastomeric chain takes was 8 mm (Group I). As we stretched the chain for 24 hours in the air and submerged it in “Sodium Fluoride” “mouthwash”, i.e., Group II A, the permanent “elongation” increased to 9.91 ± 1.34 mm (by 24% of its initial length) and when there is no exposure to “mouthwash”, i.e., Group II B, the “elongation” is increased to 9.84 ± 0.20 mm (by 23% of its initial length). We can see that the reduction is seen in both subgroups A and B, but the percentage “elongation” is slightly more increased in

Group II A (by 24%) as compared to Group II B (by 23%). When the “elastomeric chains” were extended in the mouth for 24 hours, we observed that the increase in the “elongation” was even higher. Group III A (E-chain in the mouth for 24 hours and subjected to “mouthwash”) has a percentage “elongation” of 53.3% mm and Group III B (E-chain in the mouth for 24 hours and no exposure) has a percentage “elongation” of 51.9%. A similar pattern was observed here as well. But we can also see that the percentage “elongation” tested in-vivo (Group III A and B) are comparatively higher than the groups tested in-vitro (Group II A and B). On further loading the chain for 3 weeks intraorally, we observed that there was a significant increase in the “elongation” of “elastomeric chains” with “mouthwash” (Group IV A = 14.23 ± 0.93 mm; elongated by 80%) and without “mouthwash” (Group IV B = 13.95 ± 1.22 mm; elongated by 74.4%).

DISCUSSION

“Elastomeric chains” gained popularity among orthodontists in the 1960s because of its simplicity of use, reduced chair-side time, low price, and high flexibility.^{12,13} “Elastomeric chains” provide retractive force to close generalized spaces or for movement of the teeth into the extraction site. But they also lead to poor oral hygiene, get discoloured and suffer from rapid loss of force and undergo permanent deformation as a result of stress relaxation, causing a steady loss of its effectiveness.^{1,3,5-7,12,13}

Oral hygiene concerns have yet to be resolved because of the “elastomeric chain” stretched around the bracket, which increases the likelihood of plaque accumulation and white spot lesions as the area is not easily cleansable. White spot lesions refer to the opacities that are caused by demineralization of enamel and are usually seen in the caries-prone regions around the bracket margins and gingival third of the teeth.¹¹ White spots were found in 5-8% to 44% of anterior teeth and 7.7 to 71% of posterior teeth in patients undergoing orthodontic treatment. Given that poor oral hygiene generally makes successful orthodontic treatment challenging, it is necessary to make the patient understand by demonstrating a personalised model of prophylactic measures for their education. The fluoride in the saliva and in plaque can cause remineralization of the enamel and can start reversing the early carious lesions. Hence the use of “Sodium Fluoride” mouth rinses has been popularized to reduce the occurrence of white spot lesions in patients undergoing orthodontic therapy. As a result, the orthodontist must understand the tensile properties of the “elastomeric chains” when used with and without “mouthwash”, as well as the effect of oral fluids to the internal structure of these “elastomeric chains”. In our study, we have assessed

the effect of “Sodium Fluoride” “mouthwash” (0.05%) on the “tensile strength” and percentage “elongation” of “elastomeric chains” in-vitro setting and in-vivo setting.

The inability of the “elastomeric chain” to apply a constant force over a prolonged period is its most important drawback. However, before delving into the properties of “elastomeric chains” and how the external environment affects them, it is necessary to first define the mechanical properties they possess. Beginning with the proportional limit, this is the region of the stress-strain curve that follows Hook's law, which states that stress is always proportionate to strain within the elastic limit. The elastic limit refers to the threshold point at which the material reverts to its original position and shape even after the load applied to it is fully removed. Beyond this point, the load is unable to come back to its initial position; a plastic deformation then develops. The yield point, also known as the yield stress point, is the point when a material undergoes irreversible deformation, or when it becomes permanently deformed. The maximal stress that a material can endure before failing, or breaking, is known as the ultimate stress point. Tensile refers to a material's characteristic when it is under tension. The material stretches as a result of forces that are applied perpendicular to the axis of force. The term "tensile force" refers to this force. Tensile stress is caused by the external force exerted per unit area of a material, which causes it to stretch. “Tensile strength” is the maximum load, pulling force, or tensile force that the material will be able to withstand without fracturing when stretched. percentage “elongation” is the amount that a material would deform plastically and elastically after stretching or when it has passed the yield point. To calculate the percentage “elongation”, the final length of the material is compared to its initial length and multiplied by 100. The “elastomeric chains” are polyurethanes that have an elastic-like behaviour, i.e., the tendency to come back to its initial length when

stretched. The reduction in entropy brought on by a macromolecular chain's distortion from its most likely conformation produces the restoring force that causes this type of elastic behaviour.³³ Each “elastomeric chain” module swells as a result of oral fluid absorption in the oral cavity, which may change the specimen's final length. Therefore, it is crucial to assess the percentage “elongation” of the “elastomeric chains” both in-vitro settings as well as in-vivo settings to determine how changes in the internal structure of the modules are occurring as well as how the presence of oral fluids affects the degree of deformation. Additionally, “elongation” of these modules has been reported to reduce tensile force, thereby decreasing the effectiveness of this system for tooth retraction.⁵

This study's findings are dependent on time, how long the “elastomeric chain” was stretched out and maintained, exposure to “Sodium Fluoride” “mouthwash”, and whether the tests were conducted intraorally or outside, which may influence the tensile properties of the “elastomeric chains”. The “tensile strength” was measured in newton (N) and percentage “elongation” was given in percentage (%) and the length of the elongated chain was measured in millimeters (mm).

On comparison of the Group I (as received) “elastomeric chain” (Optima Flexichain Latex-free, USA) to the “elastomeric chain” stretched for 24 hours (Group II A, II B, III A, III B), there was a decrease in the “tensile strength” of the chains, although the decrease was statistically insignificant. Elaides et al.⁵ conducted a study in which they compared the “tensile strength” of different elastomeric brands after 24 hours and 3 weeks, where he extended the “elastomeric chains” to 50% and proposed that the alteration in “tensile strength” between the control group (as-received state) and when the “elastomeric chains” 50% extended in the air could be caused by

changes in the molecular arrangement of the component of the materials. Our findings indicate that there was no statistically significant difference in the internal structure of the chains after 24 hours, despite the fact that we have stretched the chain by 100% of its original length. However, no studies have yet been done to compare the “tensile strength” of “elastomeric chains” after 24 hours intraorally or exposed to air. We found a significant difference in the percentage “elongation” of the stretched “elastomeric chains” when compared to the group I (as-received) samples in this study. In both in-vivo and in-vitro settings, the change was observed in all groups after 24 hours with and without “mouthwash”. This implies that after stretching by 100%, the “elastomeric chain” becomes permanently deformed, i.e., it cannot come back to its initial length, which will affect the force applied by the elastomeric chain for retraction. A number of studies have confirmed this type of finding that an elastomeric chain experiences the greatest amount of force loss after 24 hours.^{19-21, 25-28, 31} Since “elastomeric chains” are frequently used in orthodontic practice, the problem of “force decay” in elastomeric components is of particular interest to researchers because it presents a serious clinical issue on a daily basis. Eliades et al.³³ have proposed that the trend toward higher “elongation” seen in open “elastomeric chains” may be explained by increased load concentration and subsequent “elongation” at intermodular link region. In a study by C. Baratieri et al.⁷, they found that for Memory Chains (manufactured by American Orthodontics, Sheboygan, WI, USA) and Super Slick Chains (manufactured by TP Orthodontics, La Porte, IN, USA), the force decrease after 24 hours was not statistically significant. Kersey et al.⁴⁸ assessed the strength of elastomeric and found that the “force decay” after 1 day was approximately 17% and the force generated was less than what the manufacturer claimed. According to Mikulewicz et al.⁴⁹, different elastic materials have different

rates of force relaxation after 24 hours, ranging from 5.7 to 17.7%. Kim et al.⁹ found that from 1 hour to 1 day, there was a significant “force decay” for all groups in their study. “Force decay” in the unstretched control group averaged 28.7 g (8.0%) throughout, whereas it varied between 24.3 and 27.8 g (7.1% to 8.1%) in the equivalent pre-stretched groups.

In the present study, when Group I (as-received) is compared with Group IV A and B (3 weeks in mouth), it was observed that there was a significant decrease in “tensile strength” of the “elastomeric chains” which suggests that the “elastomeric chains” cannot apply substantial forces for movement of the teeth after 3 weeks. According to a study on “elastomeric chains” by Baty et al.¹⁶, delivering continuous force over a 3- to 4-week period with biologically acceptable force levels is practical and affordable. According to Kim et al.⁹, changing the “elastomeric chains” before a 4-week interval is not crucial from a clinical standpoint. We observed that in our study, the “elastomeric chains” showed a significant percentage “elongation” when Group III A (24 hours intraorally with “mouthwash”) is compared with Group IV A (3 weeks intraorally with “mouthwash”) and when Group III B (24 hours intraorally with no exposure) is compared with Group IV B (3 weeks intraorally with no exposure). This suggests that the “elastomeric chain” underwent further permanent deformation, and because of the “elongation” of the modules in the chain, it causes a decrease in the force that is applied by these “elastomeric chains” and further reduces their efficiency clinically in orthodontic practice. Similar results were obtained for the “tensile strength”, when Group III A (24 hours intraorally with “mouthwash”) was compared with IV A (3 weeks intraorally with “mouthwash”) and when Group III B (24 hours intraorally with no exposure) was compared with group IV B (3 weeks intraorally with no exposure), we observed a significant decrease in the “tensile

strength”. This implies that from 24 hours to 3 weeks, the “elastomeric chains” lose “tensile strength” steadily and gradually, and thus may be unable to apply significant forces for tooth movement. C. Baratieri et al. ⁷ concluded that only enhanced chains (MC and SSC) can maintain a force system of 100 grams for tooth movement after 3 weeks. According to De Genova et al. ²⁶, Ormco Power Chain (long) produced significantly low forces after a 21-day interval, which were insufficient for substantial tooth movement. In contrast, Rocky Mountain and TP Orthodontics produced high forces initially and maintained force values within the clinically advised ranges for retraction. However, we believe the reason could be, the reason could be because of the higher initial forces used, which ranged from 240.8 to 436.0 grams. In contrast, the force needed to retract teeth is between 150 and 200 grams, so it can be concluded that there was a significant decrease in force after 3 weeks. A study done by Kardach et al. ¹⁴ agreed that the elastic chains used in orthodontic treatment should be replaced every four weeks so that the force value remains reasonably constant. According to earlier studies, a significant permanent of force loss occurred within the first 24 hours, followed by three weeks of steady and gradual loss of force. ^{19, 25-26, 34, 36} This finding is consistent with what we observed in our research.

In our research, we noticed that stretching “elastomeric chains” in the mouth (Group III and Group IV) rather than in the air (Group II) resulted in lower “tensile strength” and slightly higher values of percentage “elongation”. This implies that the tendency toward permanent deformation or weakening of the “elastomeric chains” is more pronounced in an in-vivo setting. This may be because saliva is present in the oral cavity, along with other factors that can cause the chains to absorb fluid and swell, changing their molecular configurations and causing further “elongation” and hence resulting in loss of force. This has been confirmed by the systematic review by

Andhare et al.⁴⁷, who reported that although the difference wasn't statistically significant, more “force decay” was seen in in-vivo studies compared to in-vitro studies. He concluded that the oral environment could affect how quickly elastic chains/modules lose their force. Huget et al.²² concluded from their data that the concurrent water sorption of the “elastomeric chain” might be to blame for the load decay of “elastomeric chains” for water storage periods of 1 and 7 days in their study. According to Taloumis et al.¹⁷, samples of unstretched elastomeric ligatures showed that dimensional changes were partially brought on by moisture sorption, but they came to the conclusion that it also depended on the thickness and inside diameter of the elastomeric materials. The “force decay” of stretched chains which were stored in air, and water, and placed in the mouth was compared in 1978 by Ash and Nikolai²⁸. They claimed that chains kept in air showed significantly less “force decay” after half an hour as compared to “elastomeric chains” kept in an in vivo environment. According to a study by Storey and Smith⁵⁰, the rate at which in vivo chains degraded was affected by factors like temperature changes in the mouth, salivary enzymes, oral hygiene practices, and mastication.

According to our present study, it was observed that the “tensile strength” was not significantly reduced in groups that were submerged in “Sodium Fluoride” “mouthwash” (Group II A, III A and IV A) as compared to unsubmerged groups (Group II B, III B and IV B). In a previous study, it was claimed that “mouthwashes” had a detrimental effect on the “tensile strength” of O-rings employed for overdenture attachment and the force required to deliver orthodontic “elastomeric chains”.^{2, 52} In our current research, when the percentage “elongation” was compared within subgroups (i.e., Group II A & II B, III A & III B and IV A & IV B), it was found that the difference was not statistically significant, suggesting that even though the

“elongation” is higher in the group exposed to “mouthwash”, “Sodium Fluoride” “mouthwash” has no effect on the plastic deformation of these “elastomeric chains”. According to Phukaoluan et al.⁵⁴, three commercial types of “mouthwash” (Colgate Plax, Listerine, and Fluocaril) had no impact on the molecular structure of polymeric orthodontic ligature ties. The SEM images of the microscopic anatomy of the sample after “mouthwash” rinsing clearly display topographical changes or the presence of porous defects. The results also show that rinsing the “elastomeric chains” with “mouthwash” lowered the maximal force and displacement of the samples substantially.⁵⁴⁻⁵⁶

“Sodium Fluoride” increases enamel remineralization and increases its resistance to acid attack. When weak acids (Hydrofluoric acid) and strong bases (Sodium Hydroxide) interact, “Sodium Fluoride” is produced as a basic inorganic salt.⁶⁵ When exposed to NaOH, a potent alkaline solution, some commercial elastic bands have been shown to have significantly lower maximum forces, displacement, and delivery forces.⁵⁸ This can be attributed to the reason that the use of fluoride “mouthwash” also increases the pH of saliva⁵⁷, suggesting that “mouthwash” pH may be one of the determining factors.⁵⁴ However, when this effect was seen at acidic and neutral pH levels, it was insignificant.⁵⁹

According to Menon et al.¹³, when “Sodium Fluoride” (0.04%), a constituent in PhosFlur “mouthwash”, was used for 28 days, there was a “force decay” of 69.4%, which was within the acceptable range. This is consistent with the findings of our study. In another study, three weeks of using “Sodium Fluoride” “mouthwash” resulted in 57.49% “force decay”, which was not statistically significant when compared to the unexposed group.⁶¹ These findings are consistent with the findings

of our study. Omidkhoda et al. reported “force decay” of 24% to 56% within 1 to 28 days after evaluating the “force decay” of “elastomeric chains” (Dentaurum) in “Sodium Fluoride” “mouthwash” and subsequent thermocycling. The difference in their study was highly significant when in comparison to the control group.⁶² However, the conclusion of this study differs from what we observed.

It has been established that permanent deformation plays a significant role in the decay of force of “elastomeric chains”.⁶⁷ At low temperatures or high strain rates, there would be insufficient time to mobilize the chain segments because of which, slippage does not occur, and elastomeric material typically behaves like a stiff body. However, the elastomeric material is more flexible and easier to manipulate at higher temperatures or lower strain rates, and slippage of “elastomeric chains” is the dominant phenomenon.^{5,67,19,53} In the current study, the “elastomeric chain” was stretched at a rate of 5 mm/min in the Universal Testing Machine in this study, which was significantly lower than the rapid stretching of the chain that happens before chain placement in the patient's mouth. However, this rate has been used in previous studies as well, and we are mainly concerned with the material's long-term survivability rather than its strength prior to engaging in the bracket, which varies depending on the operator. A stretched “elastomeric chain” with a high “tensile strength” is preferable for preventing premature rupture. Because stress can change the orientation of molecular groupings, greater values of these mechanical properties are always preferred for these crystalline polymers.⁵

One of the major drawbacks of in-vitro studies is the inability to reproduce fluctuations in intraoral temperature induced by various foods and beverages consumed by patients. Therefore, we have concentrated on conducting both in-vitro

and in-vivo studies to study percentage “elongation” and tensile properties in both and to comprehend the effects of the environment. Despite their disadvantages, “elastomeric chains” remain a feasible and cost-effective approach a constant force with adequate force values for 3-4 weeks so we can retract/ close spaces. “Elastomeric chains” have a force-decreasing behaviour that is controlled by a range of parameters like as design, manufacturing methods, environmental factors, colour, and so on. Because clinicians must understand the mechanical properties of any material they use, this study provides detailed information regarding the mechanical properties of “elastomeric chains” when used with and without “mouthwash”.

One drawback of the study was that there was no way of knowing if the patient was using “mouthwash” twice daily as instructed. As a result, the findings of our investigation may have been hampered. The drawback was that the “elastomeric chains” from the in-vivo groups were sent to the Praj Lab in Pune in airtight containers, but we couldn't be sure that the temperature was maintained, which could have affected our results. Another drawback is that the rate of stretching the chain in-vivo (across the crimpable hooks) and in-vitro (across the steel finishing nails) may have resulted in some “elongation” before engagement. However, because the experiment was conducted by a single operator, the bias was minimized.

CONCLUSION

The aim of our study was to evaluate the effect of “Sodium Fluoride” “mouthwash” (0.05%) on “tensile strength” and percentage “elongation” of “elastomeric chains” in the external environment and in the intraoral environment

The following conclusions can be drawn from the present study:

- “Tensile strength” of “elastomeric chains” does not decrease considerably after 24 hours of stress i.e., when stretched by 100% of its initial length, but there is a considerable drop in “tensile strength” after 3 weeks intraorally when used with and without “mouthwash”.
- The “elastomeric chains” showed a significant increase in percentage “elongation” after 24 hours and 3 weeks, in-vivo as well as in-vitro, with “mouthwash” and without “mouthwash”.
- When used with “mouthwash”, the “tensile strength” and percentage “elongation” of the “elastomeric chains” do not change significantly.
- When compared to “elastomeric chains” tested in in-vitro conditions, the “elastomeric chains” in in-vivo conditions had slightly lower “tensile strength” and marginally higher percentage “elongation” values.
- The greatest decrease in “tensile strength” was detected in Group IV A i.e., when the “elastomeric chains” were stretched in the mouth for 3 weeks while the patient was instructed to use “Sodium Fluoride” “mouthwash” (0.05%), and the greatest increase in percentage “elongation” was recorded in Group IV A.

SUMMARY

Orthodontists have always needed to close spaces created by permanent tooth extraction. “Elastomeric chains” are the most effective, simple, and cost-effective methods of closing these spaces. They provide light, consistent forces for tooth retraction and can aid in the correction of tooth rotations as well as the traction of impacted teeth. However, their ability to lose force over time is their main disadvantage.

Maintaining oral hygiene in patients undergoing orthodontic therapy has been difficult for years. To address this issue, orthodontists always advise their patients to use “mouthwash”. Many orthodontists recommend using fluoride-containing “mouthwashes” because they can minimize the incidence of tooth decay and stimulate remineralization of early carious lesions. However, “mouthwash” may have an effect on the force delivery of the “elastomeric chains”. Hence, this study was conducted with the aim to determine the effect of “Sodium Fluoride” “mouthwash” (0.05%) on the “tensile strength” and percentage “elongation” of “elastomeric chains” both in the external environment (i.e., exposed to air) and in-vivo (i.e., intraorally, in the mouth).

We employed 88 samples in this study and divided them into 4 groups, with Group I being the control or as-received samples of the “elastomeric chains”. The remaining three groups were further subdivided into two subgroups A and B. Subgroup A in Groups II, III, and IV was given “mouthwash”, while Subgroup B had no exposure to “mouthwash”.

The result showed that there was no significant difference in “tensile strength” and percentage “elongation” of “elastomeric chains” immersed in “mouthwash” and those with no exposure. The “tensile strength”, however, decreased significantly in “elastomeric chains” that were subjected to the oral environment for 3 weeks with and without “mouthwash”. Nevertheless, the percentage “elongation” was increased significantly in all the groups suggesting that the “elastomeric chains” had experienced permanent deformation.

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ANNEXURE – I - ETHICAL APPROVAL CERTIFICATE



Research and Ethics Committee
KLE V K INSTITUTE OF DENTAL SCIENCES
KLE University



Accredited 'A' Grade by NAAC Placed in Category 'A' by MHRD (GoI)

Nehru Nagar, Belagavi - 590 010, Karnataka State

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E-mail: principal@kledental-bgm.edu.in

Sl. No. : **1481**

CERTIFICATE

This is to Certify that the synopsis titled

Effects of Sodium Fluoride Mouthwash on tensile strength and percentage Elongation of Elastomeric chains at different intervals after Activation: An In-Vitro and In-Vivo Study.

Submitted by

Dr. _____ P. G. Student /

Staff, Guided by _____ from Department of

Orthodontics and Dentofacial orthopaedics.

has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study

Date : 5/5/21

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Research and Ethical Committee
KLEVK Institute of Dental Sciences
BELAGAVI.

Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURE- II – TEST REPORT

1.0 Tensile Strength

Machine Specification : Universal testing machine (Computerized, Software Based)
 Company : Star Testing Systems, India., Model : STS-248
 System Accuracy of the machine : $\pm 1\%$, C/h Speed : 5 mm/minutes.
 Initial Gauge Length : 8mm

Group 1 (As-received)									
Sr. No.	Sample ID	Tensile Strength (N)	Permanent Elongation (%)	Permanent Elongation (mm)	Sr. No.	Sample ID	Tensile Strength (N)	Permanent Elongation (%)	Permanent Elongation (mm)
1	No.1	26.65	00	8	12	No.12	27.34	00	8
2	No.2	26.85	00	8	13	No.13	28.32	00	8
3	No.3	26.95	00	8	14	No.14	27.04	00	8
4	No.4	26.06	00	8	15	No.15	26.65	00	8
5	No.5	27.24	00	8	16	No.16	27.63	00	8
6	No.6	26.95	00	8	17	No.17	26.46	00	8
7	No.7	26.06	00	8	18	No.18	26.95	00	8
8	No.8	26.85	00	8	19	No.19	26.36	00	8
9	No.9	23.42	00	8	20	No.20	26.26	00	8
10	No.10	27.93	00	8	21	No.21	26.25	00	8
11	No.11	26.16	00	8	22	No.22	26.15	00	8
Average							26.66	00	8

Group : II A 24 Hrs. in Air with Mouthwash					Group : II B 24 Hrs. in Air without Mouthwash				
Sr. No	Sample ID	Tensile Strength (N)	Permanent Elongation (%)	Permanent Elongation (mm)	Sr. No	Sample ID	Tensile Strength (N)	Permanent Elongation (%)	Permanent Elongation (mm)
1	No.1	27.04	26.30	10.104	1	No.1	26.26	17.71	9.416
2	No.2	26.61	19.03	9.5224	2	No.2	26.77	22.12	9.7696
3	No.3	27.83	29.23	9.838	3	No.3	26.95	20.00	9.6
4	No.4	25.24	22.98	9.838	4	No.4	26.55	25.68	10.054
5	No.5	26.06	26.78	10.142	5	No.5	26.77	23.18	9.8544
6	No.6	26.32	25.60	10.048	6	No.6	26.67	26.76	10.140
7	No.7	27.73	16.43	9.3144	7	No.7	27.34	22.45	9.796
8	No.8	26.06	21.69	9.7592	8	No.8	30.38	25.22	0.017
9	No.9	26.16	28.48	10.278	9	No.9	25.59	23.78	9.9024
10	No.10	26.75	31.39	10.511	10	No.10	24.01	22.64	9.8112
11	No.11	26.10	21.38	9.710	11	No.11	25.81	23.75	9.9
Average		26.53	24.48	9.915	Average		26.58	23.02	9.8419

Group : III A 24 Hrs. in Mouth with Mouthwash					Group : III B 24 Hrs. in Mouth without Mouthwash				
Sr. No.	Sample ID	Tensile Strength (N)	Permanent Elongation (%)	Permanent Elongation (mm)	Sr. No.	Sample ID	Tensile Strength (N)	Permanent Elongation (%)	Permanent Elongation (mm)
1	No.1	27.93	60.66	12.852	1	No.1	27.42	24.50	9.96
2	No.2	26.95	58.85	12.708	2	No.2	25.48	45.01	11.60
3	No.3	27.63	59.19	2.735	3	No.3	25.87	64.76	13.18
4	No.4	25.57	62.15	12.972	4	No.4	26.10	51.94	12.155
5	No.5	25.57	42.71	11.416	5	No.5	26.61	55.65	12.452
6	No.6	27.34	50.73	12.058	6	No.6	27.44	50.02	12.001
7	No.7	27.63	55.46	12.436	7	No.7	25.77	44.69	11.575
8	No.8	24.69	45.01	11.60	8	No.8	26.85	52.65	12.212
9	No.9	26.36	46.32	11.705	9	No.9	26.91	62.89	13.031
10	No.10	24.69	58.85	12.708	10	No.10	26.55	57.56	12.604
11	No.11	27.04	46.84	11.747	11	No.11	26.81	61.80	12.944
Average		26.49	53.34	12.267	Average		26.52	51.95	12.1558

Group : IV A 3 Weeks. in Mouth with Mouthwash					Group : IV B 3 Weeks. in Mouth without Mouthwash				
Sr. No.	Sample ID	Tensile Strength (N)	Permanent Elongation (%)	Permanent Elongation (mm)	Sr. No.	Sample ID	Tensile Strength (N)	Permanent Elongation (%)	Permanent Elongation (mm)
1	No.1	25.18	77.56	14.208	1	No.1	27.34	85.68	14.854
2	No.2	24.01	82.40	14.592	2	No.2	24.89	81.79	14.543
3	No.3	24.89	86.78	14.942	3	No.3	26.06	98.74	15.899
4	No.4	23.71	80.83	14.466	4	No.4	24.59	77.38	14.190
5	No.5	25.57	79.93	14.394	5	No.5	26.36	88.80	15.104
6	No.6	24.89	45.20	11.616	6	No.6	26.16	46.49	11.719
7	No.7	26.75	84.10	14.728	7	No.7	24.99	64.75	13.18
8	No.8	24.40	87.44	14.995	8	No.8	24.79	57.07	12.5656
9	No.9	22.54	78.90	14.312	9	No.9	22.63	62.53	13.002
10	No.10	27.24	81.39	14.511	10	No.10	24.01	78.90	14.312
11	No.11	25.18	72.51	13.800	11	No.11	25.08	76.61	14.1336
Average		24.94	77.91	14.2331	Average		25.17	74.43	13.9547

Note : i) % Elongation calculated from following formula :

$$\% \text{ Elongation} : [(L-L_0) / L_0] \times 100$$

Where L : Initial Length of sample, L₀ : Length after removal from 16mm stretch.

ii) Conditioning of samples was done by

Testing is carried out at Praj Metallurgical Laboratory, Pune (Maharashtra)

ANNEXURE – III – PATIENT CONSENT FORM

KLE UNIVERSITY'S KLE VK INSTITUTE OF DENTAL SCIENCES,

BELAGAVI –590010.

CONSENT FORM

**EFFECT OF SODIUM FLUORIDE MOUTHWASH ON TENSILE
STRENGTH AND PERCENTAGE ELONGATION OF ELASTOMERIC
CHAINS AT DIFFERENT INTERVALS AFTER ACTIVATION**

OPERATOR: DR.

PURPOSE OF THE STUDY: You are requested to take part in a clinical study that is being conducted to assess the changes in mechanical properties of orthodontic Elastomeric Chains using sodium fluoride mouthwash at different time intervals. The results obtained from the study will be used for evaluating if sodium fluoride mouthwash is suitable to be used with orthodontic treatment and to assess if any changes in the mechanical properties of Elastomeric Chains are observed.

PROCEDURE OF THE STUDY: Should you wish to participate, you will be prescribed a sodium fluoride mouthwash (Colgate Plax) twice daily (i.e., once in the morning and once at night) for three weeks. You will have to visit our dental hospital 24 hours after and 3 weeks post the Elastomeric Chain placement in addition to your regular orthodontic appointments. Elastomeric Chains being used at a specific stage of your treatment will be used to assess its mechanical properties.

I, _____ aged _____ have been informed about my involvement in the study:

1. I agree to give my personal details like name, age, sex, address, and the details required for the study to the best of my knowledge.
2. I am informed about the procedure and that I will be undergoing the procedure. I agree and give my consent to the orthodontist for procedure.
3. I permit the dentist to utilize the information given by me and results obtained from this study for presentation and publication purpose.
4. I will not claim any returns for my cooperation in the study, even if it is being sponsored by any agency. I am participating with my own will and wish.
5. I will follow the instructions given by the doctor.
6. During the study, if I wish to resign from the study, I am free to do so and my treatment will still be completed in the department.

In my full consciousness and presence of mind, after understanding all the procedure in my vernacular language, I am willing and give my consent to participate in this study.

Date:

Place:

Patient's Signature

Signature of witness

ಕೆಎಲ್‌ಇ ವಿಶ್ವವಿದ್ಯಾಲಯದ ಕೆಎಲ್‌ಇ ವಿಕೆ ಇನ್‌ಸ್ಟಿಟ್ಯೂಟ್ ಆಫ್ ಡೆಂಟಲ್

ಸೈನ್ಸಸ್,

ಬೆಳಗಾವಿ-590010

ಒಪ್ಪಿಗೆ ಪತ್ರ

ಸಕ್ರಿಯತೆಯ ನಂತರ ವಿವಿಧ ಮಧ್ಯಂತರಗಳಲ್ಲಿ ಎಲಾಸ್ಟೊಮೆರಿಕ್

ಸರಪಳಿಗಳ ಟೆನ್ಸಿಯಲ್ ಬಲ ಮತ್ತು ಶೇಕಡಾವಾರು ಪ್ರಮಾಣದಲ್ಲಿ

ಸೋಡಿಯಂ ಫ್ಲೋರೈಡ್ ನ ಪರಿಣಾಮಗಳು

ಆಪರೇಟರ್: **ಡಾ.**

ಅಧ್ಯಯನದ ಉದ್ದೇಶ:

ವಿವಿಧ ಸಮಯಗಳಲ್ಲಿ ಸೋಡಿಯಂ ಫ್ಲೋರೈಡ್ ಮೌತ್ ವಾಶ್ ಅನ್ನು ಬಳಸಿಕೊಂಡು ಆರ್ಥೋಡಾಂಟಿಕ್ ಎಲಾಸ್ಟೊಮೆರಿಕ್ ಚೈನಿಸ್ ನ ಯಾಂತ್ರಿಕ ಗುಣಲಕ್ಷಣಗಳ ಬದಲಾವಣೆಗಳನ್ನು ನಿರ್ಣಯಿಸಲು ನಡೆಸಲಾಗುತ್ತಿರುವ ಒಂದು ವೈದ್ಯಕೀಯ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮನ್ನು ವಿನಂತಿಸಲಾಗಿದೆ. ಅಧ್ಯಯನದಿಂದ ಪಡೆದ ಫಲಿತಾಂಶಗಳನ್ನು ಸೋಡಿಯಂ ಫ್ಲೋರೈಡ್ ಮೌತ್ ವಾಶ್ ಅನ್ನು ಆರ್ಥೋಡಾಂಟಿಕ್ ಚಿಕಿತ್ಸೆಯೊಂದಿಗೆ ಬಳಸಲು ಯೋಗ್ಯವಾಗಿದೆಯೇ ಮತ್ತು ಎಲಾಸ್ಟೊಮೆರಿಕ್ ಚೈನ್ಸ್ ನ ಯಾಂತ್ರಿಕ ಗುಣಲಕ್ಷಣಗಳಲ್ಲಿ ಏನಾದರೂ ಬದಲಾವಣೆಗಳನ್ನು ಕಂಡುಕೊಳ್ಳಲಾಗಿದೆಯೇ ಎಂಬುದನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲು ಬಳಸಲಾಗುತ್ತದೆ.

ಅಧ್ಯಯನದ ವಿಧಾನ:

ನೀವು ಭಾಗವಹಿಸಲು ಬಯಸಿದರೆ, ಮೂರು ವಾರಗಳ ಕಾಲ ದಿನಕ್ಕೆ ಎರಡು ಬಾರಿ (ಅಂದರೆ, ಬೆಳಿಗ್ಗೆ ಮತ್ತು ರಾತ್ರಿ ಒಂದು ಬಾರಿ) ಸೋಡಿಯಂ ಫ್ಲೋರೈಡ್ ಮೌತ್ ವಾಶ್ (ಕೋಲ್ಗೇಟ್ ಪ್ಲೇಕ್ಸ್) ಅನ್ನು ಶಿಫಾರಸು ಮಾಡಲಾಗುತ್ತದೆ. ನಿಮ್ಮ ನಿಯಮಿತ ಆರ್ಥೋಡಾಂಟಿಕ್ ಅಪಾಯಿಂಟ್‌ಮೆಂಟ್ ಗಳ ಜೊತೆಗೆ ಎಲಾಸ್ಟೊಮೆರಿಕ್ ಚೈನ್ಸ್ ಪ್ಲೇಸ್ಮೆಂಟ್ ನ ನಂತರದ 24 ಗಂಟೆಗಳ ನಂತರ ಮತ್ತು 3 ವಾರಗಳ ನಂತರ ನೀವು ನಮ್ಮ ದಂತ ಆಸ್ಪತ್ರೆಗೆ ಭೇಟಿ ಕೊಡಬೇಕಾಗುತ್ತದೆ. ನಿಮ್ಮ ಚಿಕಿತ್ಸೆಯ ನಿರ್ದಿಷ್ಟ ಹಂತದಲ್ಲಿ ಬಳಸಲಾಗುವ ಎಲಾಸ್ಟೊಮೆರಿಕ್ ಚೈನುಗಳನ್ನು ಅದರ ಯಾಂತ್ರಿಕ ಗುಣಲಕ್ಷಣಗಳನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲು ಬಳಸಲಾಗುತ್ತದೆ.

ನಾನು, _____ ವಯಸ್ಸಿನ _____

ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆಯ ಬಗ್ಗೆ ತಿಳಿಸಲಾಗಿದೆ:

1. ನನ್ನ ವೈಯಕ್ತಿಕ ವಿವರಗಳಾದ ಹೆಸರು, ವಯಸ್ಸು, ಲಿಂಗ, ವಿಳಾಸ, ಮತ್ತು ಅಧ್ಯಯನಕ್ಕೆ ಬೇಕಾದ ವಿವರಗಳನ್ನು ನನ್ನ ಜ್ಞಾನದ ಅತ್ಯುತ್ತಮವಾಗಿ ನೀಡಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ.
2. ಕಾರ್ಯವಿಧಾನದ ಬಗ್ಗೆ ನನಗೆ ತಿಳಿಸಲಾಗಿದೆ ಮತ್ತು ನಾನು ಕಾರ್ಯವಿಧಾನಕ್ಕೆ ಒಳಗಾಗುತ್ತೇನೆ. ಕಾರ್ಯವಿಧಾನಕ್ಕಾಗಿ ಆರ್ಥೋಡಾಂಟಿಸ್ಟ್‌ಗೆ ನಾನು ಒಪ್ಪುತ್ತೇನೆ.
3. ದಂತವೈದ್ಯರಿಗೆ ನಾನು ನೀಡಿದ ಮಾಹಿತಿ ಮತ್ತು ಈ ಅಧ್ಯಯನದಿಂದ ಪಡೆದ ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಸ್ತುತಿ ಮತ್ತು ಪ್ರಕಟಣೆ ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಿಕೊಳ್ಳಲು ನಾನು ಅನುಮತಿ ನೀಡುತ್ತೇನೆ.
4. ಯಾವುದೇ ಏಜೆನ್ಸಿಯಿಂದ ಪ್ರಾಯೋಜಿಸಲ್ಪಟ್ಟಿದ್ದರೂ ಸಹ, ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಸಹಕಾರಕ್ಕಾಗಿ ನಾನು ಯಾವುದೇ ಆದಾಯವನ್ನು ಪಡೆಯುವುದಿಲ್ಲ. ನಾನು ನನ್ನ ಸ್ವಂತ ಇಚ್ಛೆ ಮತ್ತು ಆಶಯದೊಂದಿಗೆ ಭಾಗವಹಿಸುತ್ತಿದ್ದೇನೆ.
5. ವೈದ್ಯರು ನೀಡಿದ ಸೂಚನೆಗಳನ್ನು ನಾನು ಅನುಸರಿಸುತ್ತೇನೆ.
6. ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ, ನಾನು ಅಧ್ಯಯನಕ್ಕೆ ರಾಜೀನಾಮೆ ನೀಡಲು ಬಯಸಿದರೆ, ನಾನು ಅದನ್ನು ಮಾಡಲು ಮುಕ್ತನಾಗಿರುತ್ತೇನೆ ಮತ್ತು ನನ್ನ ಚಿಕಿತ್ಸೆಯು ಇಲಾಖೆಯಲ್ಲಿ ಇನ್ನೂ ಪೂರ್ಣಗೊಳ್ಳುತ್ತದೆ.

ನನ್ನ ಪೂರ್ಣ ಪ್ರಜ್ಞೆ ಮತ್ತು ಮನಸ್ಸಿನ ಉಪಸ್ಥಿತಿಯಲ್ಲಿ, ನನ್ನ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿನ ಎಲ್ಲಾ ಕಾರ್ಯವಿಧಾನಗಳನ್ನು ಅರ್ಥಮಾಡಿಕೊಂಡ ನಂತರ, ನಾನು ಸಿದ್ಧನಾಗಿದ್ದೇನೆ ಮತ್ತು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನನ್ನ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡುತ್ತೇನೆ.

ದಿನಾಂಕ:

ಸ್ಥಳ:

ರೋಗಿಯ ಚಿಹ್ನೆ

केएलई वदियापीठचे केएलई व्ही के इन्सटिट्यूट ऑफ दंत वजिजान,

बेलगावी -590010.

संमती पत्र

सक्रयितेनंतर वेगवेगळ्या अंतरावरील तन्य शक्ती आण इलेस्टोमेरिक साखळ्यांची
टक्केवारी वाढवण्यावर माऊथवॉशचे परणाम

संचालक:

अभ्यासाचा उद्देश:

तुम्हाला वेगवेगळ्या वेळी सोडियम फ्लोराईड माऊथवॉश वापरून सनातनी लवचकि
साखळीच्या यांत्रिक गुणधर्मांमध्ये झालेल्या बदलांचे मूल्यमापन करण्यासाठी केल्या
जाणाऱ्या वैद्यकीय अभ्यासात सहभागी होण्याची वनिती केली जाते. सोडियम फ्लोराईड
माऊथवॉश ऑर्थोडॉन्टिक उपचारांसह वापरणे योग्य आहे का याचे मूल्यमापन
करण्यासाठी आणिलवचकि साखळीच्या यांत्रिक गुणधर्मांमध्ये काही बदल आढळले
आहेत का याचे मूल्यमापन करण्यासाठी अभ्यासातून मळिलेले नषिकर्ष वापरले जातील.

अभ्यासाची प्रक्रिया:

जर तुम्हाला सहभागी व्हायचे असेल तर तुम्हाला तीन आठवड्यांसाठी दविसातून दोनदा
सोडियम फ्लोराईड माऊथवॉश (कोलगेट प्लॅक्स) लहिन दिले जाईल. तुमच्या नियमति
ऑर्थोडॉन्टिक अपॉइंटमेंट्सव्यतरिकित लवचकि चेन प्लेसमेंटनंतर तुम्हाला आमच्या डेंटल
हॉस्पिटिलला 24 तास आण 3 आठवड्यांनंतर भेट द्यावी लागेल. आपल्या उपचाराच्या
वशिष्ट टप्प्यावर वापरल्या जाणाऱ्या लवचकि साखळ्या त्याच्या यांत्रिक गुणधर्मांचे
मूल्यांकन करण्यासाठी वापरल्या जातील.

मी, _____ वय-वर्ष _____

खालील अभ्यासामध्ये सामील असल्याची मला माहिती दिली आहे:

1. माझे वैयक्तिक तपशील जसे की नाव, वय, लग्न, पत्ता आणि अभ्यासासाठी आवश्यक असलेल्या तपशीलांना माझ्या सर्वोत्तम माहिती देण्यासाठी मी सहमत आहे.
2. कार्यपद्धतीविषयी मला माहिती देण्यात आली आहे व माझ्याकडे अशी प्रक्रिया सुरू आहे. मी सहमत आहे आणि प्रक्रियेसाठी ऑर्थोडोन्टसिटला माझी संमती देत आहे.
3. मी दंतचिकित्सकांकडून माझ्याद्वारे दिलेली माहिती आणि अभ्यासामधून प्राप्त झालेल्या सादरीकरणासाठी आणि प्रकाशनाच्या उद्देशाने वापरण्याची परवानगी देत आहे.
4. अभ्यासाच्या माझ्या सहकार्यासाठी मी कोणत्याही परताव्याचा दावा करणार नाही, जरी ती कोणत्याही एजन्सीने प्रायोजित केली असेल. मी माझ्या स्वतःच्या इच्छेने आणि इच्छेने सहभाग घेत आहे.
5. मी डॉक्टरांनी दिलेल्या सूचनांचे पालन करेन.
6. अभ्यासादरम्यान, जर मला अभ्यासाचा राजीनामा द्यायचा असेल तर मी तसे करण्यास मोकळे आहे आणि तिरीही माझे उपचार विभागात पूर्ण होतील.

माझ्या पूर्ण चेतने आणि मनाच्या उपस्थितीत, माझ्या स्थानिक भाषेतील सर्व प्रक्रिया समजल्यानंतर मी इच्छुक आहे आणि अभ्यासामध्ये भाग घेण्यास मी संमती देतो.

तारीख:

ठिकाण:

गुणाची सही